

October 2017

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Recommended Citation

Richard W. Garnett (1996) "Why Informed Consent? Human Experimentation and the Ethics of Autonomy," *The Catholic Lawyer*. Vol. 36 : No. 4 , Article 5.

Available at: <https://scholarship.law.stjohns.edu/tcl/vol36/iss4/5>

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WHY INFORMED CONSENT? HUMAN EXPERIMENTATION AND THE ETHICS OF AUTONOMY

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*Any man's death diminishes me,
because I am involved in mankind;
and therefore never send to know
for whom the bell tolls;
it tolls for thee.¹*

*A familiar figure ... haunts modern society.
We've never actually met him, but we all know him.
This elusive figure is the free agent, bound only by his
own choices. He chooses a career, a spouse, a religion, a
lifestyle, and more. He animates our moral and political
arguments, our very idea of what a person is, and our
social lives. A figure at once profound and banal,
he poses a host of intriguing puzzles.²*

I. INTRODUCTION

Not long ago, the welfare reform debate took a provocative

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¹ J. Donne, *Devotion XVII*, in JOHN DONNE: SELECTED POETRY AND PROSE 166 (T. Craik & R. Craik, eds. 1986).

² DON HERZOG, *HAPPY SLAVES: A CRITIQUE OF CONSENT THEORY* ix (1989).

turn. New Jersey welfare recipients challenged the state's Family Cap rule, which denied additional cash aid to parents who conceive children while on welfare.³ Welfare rights activists argued that the rule "with[held] benefits to see if [this would] alter human behavior."⁴ They insisted that the innovative, but stern, Family Cap rules were effectively experiments on welfare recipients without their consent.⁵

This is a powerful argument. After all, consent enjoys talismanic—if not sacramental—status in modern life and thought; it is our "master concept."⁶ But why? Why should consenting mean so much that by comparison other ideas and ideals often mean so little?⁷ The power of consent lies deeper than its everyday meaning of "Sure, go ahead" or "Let's do it."⁸ It prompts more questions than it answers: May someone else say, "Sure, go ahead. Do something to *him*?" If I consent to something now,

³ C.K. v. Shalala, 883 F. Supp. 991, 997 (D.N.J. 1995). The Family Cap provision was challenged on the ground that, *inter alia*, it presented a danger to the plaintiffs' well-being and therefore, pursuant to 42 U.S.C. § 3515b, required their written consent. *Id.* at 1008. The district court found that public benefit projects are generally exempt from the informed consent requirement in that they do not present a danger within the meaning of § 3515b. *Id.* at 1009; *accord*, *Beno v. Shalala*, 853 F. Supp. 1195, 1210 (E.D. Cal. 1993) ("as a general rule a project which changes benefit levels will not present a danger such that informed consent is required"), *rev'd on other grounds*, 30 F.3d 1057 (9th Cir. 1994).

⁴ See *Rats: Welfare Reform and Human Experimentation*, THE NEW REPUBLIC, Aug. 8, 1994, at 16.

⁵ *Id.* See C.K., 883 F. Supp. at 1008-09 (deeming New Jersey's Family Cap provision a "welfare experiment"); see also *Beno*, 853 F. Supp. at 1208 (finding that California's work incentive program modifying benefits to welfare recipients is "federally-funded 'experiment'").

⁶ Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 900 (1994) (discussing consent's role in law of contracts, torts, and health care treatment); see also Richard A. Posner, Colloquy, *The Ethical Significance of Free Choice: A Reply to Professor West*, 99 HARV. L. REV. 1431, 1431 (1986) (arguing that consent is "the fundamental tenet of classical liberalism"); Cass R. Sunstein, *Legal Interference with Private Preferences*, 53 U. CHI. L. REV. 1129, 1129 (1986) (noting that "American law generally treats private preferences as the appropriate basis for social choice.").

⁷ See Robin West, *Authority, Autonomy, and Choice: The Role of Consent in the Moral and Political Visions of Franz Kafka and Richard Posner*, 99 HARV. L. REV. 384, 386 (1985) ("Consent insulates these situations from moral criticism and renders them, without more, morally attractive ... [C]onsent is a moral trump.").

⁸ When asked if he had any last words, convicted murderer Gary Gilmore is reported to have said, "Let's do it." NORMAN MAILER, *THE EXECUTIONER'S SONG* 984 (1979). Mailer's account of Gilmore's fight to waive review of his death sentence - to consent to his execution - dramatically illustrates the power of consent in our culture's imagination. *Id.*

am I forever stuck with or bound by my choice? May I delegate my power to consent or assign my consent's moral force to someone else? May I consent to anything I wish? Can everybody provide morally meaningful consent, or only those who possess or exhibit autonomy (whatever that means)?⁹

Such questions have always prompted frustratingly interminable discussion. But we continue to wrestle with them because consent and its mysteries have "an extraordinarily firm hold on our imagination [Consent] provides perhaps the single most prevalent paradigm structuring our thinking about law, society, morality and politics."¹⁰ Consent also animates other cherished but nebulous concepts. It is intimately connected to our ideas of "liberty" (I may do what I choose to do, and may refuse to consent to actions in which I do not wish to be involved); "equality" (we all get to consent); "autonomy" (I and only I may make these choices and decisions); and "dignity" (I may make these decisions because of who and what I am).¹¹

Perhaps because consent is so embedded in our moral thinking, we put it to at least two different tasks. First, consent is a basic and fundamental prerequisite of our political and social institutions and of our dealings with one another.¹² We have lost the premodern vision of the world as an organic whole, and so consent, rather than nature or design, structures the coming together, binding together, and living together of modern masterless men.¹³ This side of consent animates the political "consent

⁹ See Richard H. Fallon, Jr., Essay, *Two Senses of Autonomy*, 46 STAN. L. REV. 875 (1994) (unpacking concept of autonomy and contrasting "descriptive" with "ascriptive" autonomy.).

¹⁰ HERZOG, *supra* note 2, at 215 (describing consent theory as "a theory of a social world whose individuals make their own choices."); see also Robert A. Burt, *Democracy, Equality, and the Death Penalty*, XXXVI *Nomos* 80 (1994) (noting that the "equality principle" at core of democratic political theory "requires freely given consent as the basis of all political relations."); Sunstein, *supra* note 6, at 1129 ("American law generally treats private preferences as the appropriate basis for social choice.").

¹¹ Peter Schuck has noted that consent expresses the "primacy of individualistic values in our culture." It is "instrumental to economic efficiency, a cherished value in American culture," and it animates our pervasive "suspicion of state power." Schuck, *supra* note 6, at 900-01.

¹² See generally *supra* note 6 and accompanying text.

¹³ HERZOG, *supra* note 2, at xiii, 39-71 ("Medieval images of society as an organic whole ... were increasingly unhelpful Consent theory posed, correctly, not just as a rival view, but as a superior one."). For a beautiful description of the medieval vision, see C.S. LEWIS, *THE DISCARDED IMAGE* (1964).

theory" and permeates the rhetoric and myths of the American founding.¹⁴ It is a necessary first condition for the legitimacy of the institution or end-state that proceeds from the act of consenting.¹⁵

Consent has another job. The fact that a certain institution, result, procedure, or transaction was consented to is often pointed to as the moral justification for that institution, result, procedure, or transaction. Thus, not only is consent necessary for a moral end-state, it is also sufficient.¹⁶ Consent not only legitimates, it also justifies. Not surprisingly, this is the face of consent that resonates with libertarians and libertines.¹⁷

This "justifying" side of consent raises some timeless and thorny questions. What if people consent to activities and results which are repugnant, or even evil? Even John Stuart Mill worried about honoring consensual slavery.¹⁸ For Mill, one who enslaved himself failed to play by the rules, "missed the point" of his freedom, and could therefore be restrained without disrespect to Liberty. Today, we wonder whether a woman's consent to appear in graphic, demeaning, or even violent pornography justifies or immunizes the pornographer.¹⁹ If she appears to consent to a relationship in which she is repeatedly brutalized, does her consent stymie our efforts to stop the brutality or punish the brute?²⁰

¹⁴ See generally HERZOG, *supra* note 2, at xiv, 5-38.

¹⁵ See RICHARD POSNER, *THE ECONOMICS OF JUSTICE* 144 (1981) ("One can justify the state by imagining its formation as the product of a social contract, or one can explain it as the actual product of such a contract.").

¹⁶ *Id.*

¹⁷ See HERZOG *supra* note 2, at 233 ("In a libertarian world, contract emerges as the paradigm conception of what consent or choice amounts to."); see also ROBERT NOZICK, *ANARCHY, STATE AND UTOPIA* (1974) (discussing nature of state and its legitimate functions and justifications).

¹⁸ See J.S. MILL, *ON LIBERTY* 125-26 (Oxford University Press 1948) (1859).

¹⁹ See Jeffrey D. Goldberg, Comment, *Involuntary Servitudes: A Property-Based Notion of Abortion-Choice*, 38 UCLA L. REV. 1597, 1634 n.134 (1991) ("Consider ... some women's 'consent' to society's objectification and subordination of women through the use of pornography.").

²⁰ *Id.* ("Consider ... the 'consent' of battered women to stay with their assailants. Similar questions involve the extent to which male-dominated institutions impose cultural 'norms' that are then 'consented' to.").

Wives submit to abusive husbands; employees consent to exploitative and humiliating work environments; consumers consent to sales of defective, dangerous, and over-priced merchandise; women consent to 'date rape' and to sexual harassment on the street and on the job; religious converts submit to directives compelling consensual suicide; subjects in an experiment

These problems make us squirm a little, just as they did Mill. We have three ways out: We can say, first, "Yes, consent justifies whatever is consented to—you consented, so case closed;" second, "This particular consent is deficient—you did not really consent and so the result or action is not justified;" or third, "You consented, but your consent cannot justify this action or result." For example, Dr. Kevorkian apparently elicits consent from his subjects before helping them kill themselves.²¹ We can note the consent, shrug, and be on our way. Or, we can deconstruct the consent, scrutinizing it carefully for the indicia of autonomy—was it "knowing?," was it "informed?"—that give consent its moral force. Finally, we can say that while consent is not irrelevant (it would certainly be worse if Dr. Kevorkian's subjects did not consent), the consent does not and cannot justify either Dr. Kevorkian's act or the act of his subject.²²

Note the subtle yet crucial difference between these three options: In the first, consent is king, while the third option assumes a moral universe shaped and governed by extra-consensual considerations. The second option, however, reflects the tension between the other two. We might block the con-

consent to the dehumanizing, authoritative instruction to electrically shock other human beings; monks consensually abide by 'vows' of poverty; Zen students consensually endure assaults by their teachers; patients in therapy abide the directives of their therapists; soldiers follow the orders of their superiors; and citizens generally obey, without need of coercion, the legal injunctions of their governments.

West, *supra* note 7, at 427.

²¹ See generally Hon. Alice Gilbert, *The Legal Response to Assisted Suicide*, 20 OHIO N.U. L. REV. 673 (1994) (discussing legal response to physician-assisted suicide and including Judge Gilbert's unpublished opinion issuing permanent injunction prohibiting Dr. Jack Kevorkian from engaging in further assisted suicides).

As this essay goes to publication, the United States Supreme Court is deciding whether to join the national tumult over physician-assisted suicide. See *Compassion in Dying v. State of Washington*, 79 F.3d 790 (9th Cir. 1996) (*en banc*) (holding state's ban on physician-assisted suicide violated terminally ill patients' due process rights); *Quill v. Vacco*, 80 F.3d 716 (2nd Cir. 1996) (holding New York's statute criminalizing assisting another in committing suicide violated Equal Protection Clause of U.S. Constitution).

²² See Susan K. Jezewski, Note, *Can a Suicide Machine Trigger the Murder Statute?*, 37 WAYNE L. REV. 1921, 1329 (1991) ("Under the traditional common law, consent by the victim was never a defense to a murder charge, regardless of the intent of the victim."); see also Hans Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, 98 DAEDALUS 219, 233 (1969) (consent is a "non-negotiable minimum requirement" in human experimentation, but "not the full answer to the problem"); West, *supra* note 7, at 399 (noting that consent "may save ... transactions from being theft, slavery, or rape, but it hardly accords them positive moral value. Consensual acts ... are not morally good simply because they are not coerced.").

sented-to action, but we pay lip service to consent's justifying role by assuring ourselves that had the consent been untainted, had it been "informed," it would have had moral force. In fact, we pay lip service precisely because we often silently suspect that consent cannot and does not always justify.²³ Therefore, in difficult situations, we declare that the decision maker did not or could not really consent, that the consent was not "informed" or "knowing" or "voluntary."²⁴ Rather than admit that the consent does not and could not justify the act, we denigrate the consent and, necessarily, the consentor as well.²⁵

This is cheating; it is a subterfuge designed to hide our unease and to allow us to profess simultaneous commitment to values that often conflict.²⁶ This Article will discuss this subterfuge in the context of experimentation and research on human beings.²⁷ First, to set the stage, I will briefly discuss human experimentation, its history, and the role of consent in research ethics and regulations. Next, I will show how consent has failed to control abuses in human experimentation, and how it has actually undermined the dignity of research subjects by deconstructing their ability to make decisions. Finally, I will argue that consent cannot justify all experiments. Consent, and the ethics of autonomy its prominence reflects, is not up to the task we have assigned it. I conclude with some thoughts on an ethics of relationships, one grounded in a more robust conception of human flourishing and *telos*, which may better promote and protect our ideals in human experimentation.

There are powerful objections to this argument. First, we need research subjects, and limits on consent hamstring both Science and Progress.²⁸ This may be a price worth paying. After

²³ See Robin West, Colloquy, *Submission, Choice, and Ethics: A Rejoinder to Judge Posner*, 99 HARV. L. REV. 1449, 1449-50 (1986) (arguing that readers would not believe that people should be allowed to sell themselves into slavery or prostitution).

²⁴ See *infra* part IV.

²⁵ *Id.*

²⁶ On the use of subterfuge as a device for masking trade-offs between competing values, see GUIDO CALABRESI & PHILIP BOBBITT, *TRAGIC CHOICES* 195-99 (1978).

²⁷ Guido Calabresi has observed that consent plays two distinct roles in human experimentation. See Guido Calabresi, *Reflections on Medical Experimentation in Humans*, 98 DAEDALUS 387, 403-05 (1969).

²⁸ See Jesse A. Goldner, *An Overview of Legal Controls on Human Experimentation and the Regulatory Implication of Taking Professor Katz Seriously*, 38 ST. LOUIS U. L.J. 63 (1993) (discussing effect of regulatory scheme controlling human experimentation); Tim Friend, *Divided Over Devices: FDA Rules Force Medical Test*

all, "progress is an optional goal, not an unconditional commitment ... its tempo in particular, compulsive as it may become, has nothing sacred about it."²⁹ Second, it is charged, limits on a potential subject's power to consent to an experiment are indefensibly and offensively paternalistic.³⁰ Both the legitimating and justifying faces of consent purportedly embody and advance notions of freedom and autonomy.³¹ By curtailing consent's justificatory role, do we trample on human dignity? Maybe not. The same concern and respect for human dignity that animates and empowers consent may also require restrictions upon the unbridled search for knowledge; it may—perhaps paradoxically—preclude unlimited autonomy.

Returning to the question posed at the outset: Why does consent have such moral power? Accept for now that our deference to consent is—perhaps mistakenly—rooted in a commitment to human dignity, expressed through respect for autonomy.³² Is consent's justifying role necessarily required by this commitment to human dignity? Why have we come to think that it is? Does our dignity as persons follow from, or does it instead create and condition, our autonomy? Do we respect consent because one feature of our dignity is that we always know what is best for us? Clearly we do not:

Free individuals, going about their own business with dignity and confidence: that's what the world is all about, we think ... We are uneasily aware that the world isn't quite like that after all ... we make horrible choices all the time. Our actions are often uninformed, self-destructive, neurotically repetitive, floundering and helpless.³³

Perhaps, instead, the full brunt of the evil of which we are capable—so evident in this century of ghettos, concentration camps, killing fields, cultural revolution, eugenics, and ethnic cleansing—coupled with the modern vision of human society as an aggregate of atomistic individuals rather than an organic

Overseas, Clinical Trials in U.S. Called 'Endangered,' USA TODAY, May 10, 1995, at A1 (explaining that before medical devices are tested in humans, Food and Drug Administration requires that risky devices be proven safe in laboratory testing).

²⁹ Jonas, *supra* note 22, at 245.

³⁰ See *infra* notes 195-226 and accompanying text.

³¹ See West, *supra* note 7, at 411-12 (noting "gross disjunction between consensual acceptance of risk and the autonomous values that consent purportedly promotes").

³² See Schuck, *supra* note 6, at 939 (noting that deontological view of consent as promoting human autonomy has driven traditional doctrine of informed consent).

³³ HERZOG, *supra* note 2, at 2.

whole, has left us standing bare and exposed, with no reply to or protection from such atrocities other than a weak and hollow insistence that, in the future, "we must consent first!"³⁴ The presence of consent has thus become the assurance to ourselves that all is well. It is a marker which—we hope—indicates acceptable human relations.³⁵ But of course it does not, and so our reliance on consent is all the more poignant a subterfuge.³⁶ If consent's power to justify derives from a weary reaction to evil in an overly-individualistic world, and not from a commitment to social relations predicated on respect for human dignity, we are doomed to disappointment, and we have failed as a community.

II. HUMAN EXPERIMENTATION AND WHY WE SHOULD WORRY ABOUT IT

A. An Uneasy History

We harbor a deeply-rooted, but rarely articulated, unease with human experimentation.³⁷ During the past few years, controversy has drawn this unease to the surface of public life.³⁸ For example, in the recent debate over experimentation on made-for-

³⁴ The Nuremberg Tribunal decried the fact that "[i]n every single instance ... subjects were used who did not consent," as if the lack of consent was what made the Nazi Doctors' actions so horrible. See *United States v. Karl Brandt, et al.*, in JOSEPH GOLDSTEIN ET AL., *CRIMINAL LAW: THEORY AND PROCESS* 66, 74 (1974) [hereinafter *CRIMINAL LAW*].

³⁵ I was given this insight by Professor Robert Burt.

³⁶ See CALABRESI & BOBBITT, *supra* note 26, at 195-99 ("[I]t will become apparent that some sacrifice of values has taken place.").

³⁷ See CHARLOTTE LEVY, *THE HUMAN BODY AND THE LAW: LEGAL & ETHICAL CONSIDERATIONS IN HUMAN EXPERIMENTATION* 1 (2d ed. 1983) ("[S]ome people bristle at the very idea of experimenting with human beings and they are not willing to discuss it further.").

³⁸ See, e.g., Michael Granberry, *UC Irvine Unveils Plan for Closer Policing of Research on Humans*, L.A. TIMES, June 11, 1996, at A3 (describing university's new measures designed to prevent abusive and scandalous experiments); Julianne Malveaux, *Experiments Are Barbaric*, USA TODAY, Nov. 13, 1995, at A12 (arguing against human experimentation); *Little Harm Found in Radiation Tests: Study Says Most Subjects Shouldn't Get Compensation*, CHI. TRIB., Oct. 3, 1995, at 3 (reporting advisory panel's finding that most people subjected to government-sanctioned radiation tests during Cold War suffered little or no lasting effect); see also President William J. Clinton, Executive Order, Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission (Oct. 3, 1995); E. Cooper Brown, *Human Radiation Experiments: Statement of the Task Force on Radiation and Human Rights on the 50th Anniversary of the Nuremberg Tribunal* (Congressional Testimony, March 12, 1996).

research embryos, one objector expressed horror at such "Frankensteinian" projects; his opponent rejoined that the research "could spare enormous human suffering and help countless Americans."³⁹ A *New York Times* editorial joined the fray, proclaiming that "humans are not lettuces" to be created and discarded for purely instrumental purposes.⁴⁰ Dr. Jack Kevorkian has stirred up still more controversy by advocating extensive experimentation on anesthetized capital offenders, and by his recent acquittals on murder charges.⁴¹ The Clinton administration investigated experiments at Vanderbilt University in the 1940's in which pregnant women were given radioactive iron.⁴² A UCLA undergraduate who volunteered for experi-

³⁹ Kim Painter, *Scientists' Existential Question*, USA TODAY, Aug. 25, 1994, at D1-2 (discussing morality of experimentation on human embryos); see also Laurie McGinley, *Research That Uses Human Embryos Should Get U.S. Funding*, Panel Says, WALL ST. J., Sept. 28, 1994, at B7 (describing federal advisory panel's recommendation that researchers be allowed to produce embryos specifically for research); Richard John Neuhaus, *Don't Cross This Threshold*, WALL ST. J., Oct. 27, 1994, at A20 (cautioning against crossing threshold into embryo experimentation); Joseph Piccione, *Close This Box of Horrors*, USA TODAY, Aug. 25, 1994, at A10 (warning that embryo research will open "Pandora's box of horrors and ... future dilemmas that will in turn sacrifice good ethics to cold utilitarian standards."); *Clinton Bars Certain Funding of Embryos*, WALL ST. J., Dec. 5, 1994, at B5 (reporting President's barring of federal funding for research on embryos created solely for research purposes); *Restart Embryo Research*, USA TODAY, Aug. 25, 1994, at A10 (noting that "microscopic cluster of human cells holds a treasure-trove."); Letters to the Editor, *When is an Embryo Human?*, WALL ST. J., Nov. 14, 1994, at A11 (responding to Neuhaus by arguing that human life does not begin at conception).

⁴⁰ Arthur H. Rotstein, *Ban on Fetal-Tissue Research Challenged: Parkinson's Patients Among Suit's Plaintiffs*, ARIZ. REPUBLIC, April 30, 1996, at B1 (describing lawsuit against statute criminalizing experimentation on aborted unborn children); Mary Cantwell, *Should We Make Research Embryos? No, Humans Are Not Lettuces*, N.Y. TIMES, Nov. 25, 1994, at A36 (criticizing proposal allowing scientists to use human embryos for research purposes); but see Philip M. Boffey, *An Editorial Debate: Should We Make Research Embryos? Yes, the Gains Could Be Great*, N.Y. TIMES, Nov. 25, 1994, at A36 (arguing that research embryos hold potential for great benefit).

⁴¹ See generally JACK KEVORKIAN, *PRESCRIPTION: MEDICINE - THE GOODNESS OF PLANNED DEATH* (1991); Mark Hosenball, *The Real Jack Kevorkian*, NEWSWEEK, Dec. 6, 1993, at 28 ("Kevorkian advocated what he calls 'terminal human experimentation.'"); Brian Harmon, *Is He a Freedom Fighter or a Ghoulish Dr. Death?*, DETROIT NEWS, May 23, 1996 (describing public opinion and reaction regarding Kevorkian's acquittals and activities); Edward Walsh, *Kevorkian Critics Left With Dilemma; Legal System Failing to Halt Suicides*, WASH. POST, May 18, 1996, at A3 (discussing impact of Kevorkian acquittals on future cases and legislation).

⁴² *Clinton Apologizes for the Wrong Done in Human Radiation Testing*, CHI. TRIB., Oct. 4, 1995, at 9 ("When the government does wrong, we have a moral responsibility to admit it."); see Keith Schneider, *Scientists Share in Pain of Experiment Debates*, N.Y. TIMES, Mar. 2, 1994, at A12 ("No institution has developed a tougher

mental schizophrenia treatment has alleged that researchers foresaw and even conspired to produce his and others' schizophrenic relapses.⁴³ Researchers, ethicists, and activists continue to debate limits on testing experimental AIDS drugs.⁴⁴ And in the Persian Gulf War, unknowing soldiers were given unproved drugs and vaccines.⁴⁵

But the recent surge in awareness and discussion about hu-

stance than Vanderbilt University which contends that its scientists did nothing wrong when they recruited at least 819 pregnant women ... for a nutritional study."). The results of the radiation experiment investigation, which have angered many, found that "only a few hundred people should get medical notification, compensation, or even a personal apology from the federal government." See Danielle Gordon, *The Verdict: No Harm No Foul. Report of the Advisory Committee on Human Radiation Experiments*, BULL. OF THE ATOMIC SCIENTISTS, January, 1996, at 32.

⁴³ See James Willwerth, *Tinkering with Madness*, TIME, Aug. 30, 1993, at 40 ("Today Greg's parents believe the doctors deliberately triggered his relapse."); see also Joy Horowitz, *For the Sake of Science*, LOS ANGELES TIMES, Sept. 11, 1994, at 16 (suicide of schizophrenic UCLA research patient set off national debate on human experimentation); *Agency Faults a UCLA Study for Suffering of Mental Patients*, N.Y. TIMES, Mar. 10, 1994, at A1 ("[T]he study ... raised fundamental questions about the system for protecting patients in medical experiments.").

⁴⁴ See generally George J. Annas, *Faith (Healing), Hope and Charity at the F.D.A.: The Politics of AIDS Drug Trials*, 34 VILL. L. REV. 771 (1989) [hereinafter Annas, *Faith*] (arguing that distinction between experimental and therapeutic interventions is crucial to science and individual rights); Martin Delaney, *The Case for Patient Access to Experimental Therapy*, 159 J. INFECTIOUS DISEASES 416 (1989) (answering arguments used to justify denial of access to experimental therapy); Wendy K. Mariner, *AIDS Research and the Nuremberg Code*, in THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 286-304 (George J. Annas & Michael A. Grodin eds., 1992) [hereinafter THE NAZI DOCTORS] (detailing controversy over human research for new drugs for AIDS).

⁴⁵ In December, 1990, the FDA granted the Department of Defense a waiver from human experimentation regulations, and allowed the use of unapproved drugs and vaccines on soldiers in the Persian Gulf. See 21 C.F.R. §§ 50, 23(d) (1995). The Commissioner of Food and Drugs may determine that obtaining informed consent is not feasible in specific military operations involving combat or immediate threat of combat. See generally George J. Annas, *Mengele's Birthmark: The Nuremberg Code in United States Courts*, 7 J. CONTEMP. HEALTH L. & POL'Y 17 (1991) [hereinafter Annas, *Mengele's Birthmark*]; George Annas & Michael Grodin, *Treating the Troops*, 21 HASTINGS CTR. REP. 24 (1991). A federal court refused to enjoin implementation of the rule. See *Doe v. Sullivan*, 756 F. Supp. 12 (D.D.C. 1991) (holding that FDA's rule allowing Department of Defense to administer unapproved drugs to troops participating in Operation Desert Storm without obtaining informed consent constituted strategic military decision, advanced legitimate government interests, and did not violate due process rights), *aff'd*, 938 F.2d 1370 (D.C. Cir. 1991). But see Martha J. Burns, Note, *They Fight to Protect Our Rights; Shouldn't We Do the Same for Them? Intramilitary Immunity in Light of United States v. Stanley*, 38 DEPAUL L. REV. 127 (1988) (criticizing Supreme Court's decision that there is military immunity from suit based on lack of informed consent even in peacetime).

man experimentation⁴⁶ should not obscure the fact that medicine has a long "tinkering tradition."⁴⁷ Twentieth-century consciousness has been especially influenced by a few notorious experiments,⁴⁸ including the Tuskegee Syphilis Study, in which hundreds of black men were allowed to languish with curable syphilis;⁴⁹ the Jewish Chronic Disease Hospital study, in which researchers injected live cancer cells into unknowing patients with various chronic debilitating diseases;⁵⁰ the experiments of the Nazi doctors;⁵¹ and the recently publicized atrocities of the Japanese Army's "Unit 731," which killed thousands of Chinese in medical and germ-warfare experiments.⁵² In short, we have a

⁴⁶ See Keay Davidson, *Radiation Inquiry Opens in S.F.; Panel Probes Secret Tests on Humans*, SAN FRANCISCO EXAMINER, Oct. 12, 1994, at A6 (revealing "nation's legacy of radiation experiments on unwitting victims."); Tim Friend, *Patients Not Told Devices Experimental*, USA TODAY, Apr. 19, 1995, at A1 (disclosing that doctors implanted experimental medical devices in patients without their knowledge in violation of FDA testing rules); Philip J. Hilts, *Judge Tells Health Department to Stop Experiments on Patients*, N.Y. TIMES, March 26, 1995, at B52 (reporting that Health Department ordered to halt experiments on children and mentally ill who are incompetent to give their consent); Philip J. Hilts, *New Radiation Tests on Civilians Disclosed; Panel Finds Another, Unanticipated Facet of Cold War Experiments: Ethical Debates*, N.Y. TIMES, Oct. 12, 1994, at A10 (reporting that Presidential committee uncovered evidence of many previously unknown radiation experiments during Cold War Era).

⁴⁷ Robert A. Burt, *Why We Should Keep Prisoners from the Doctors*, 5 HASTINGS CTR. REP. 25, 26 (1975). On the history of human experimentation, see generally, Annas, *Mengele's Birthmark*, *supra* note 45 (outlining recent history of human experimentation in United States); Henry K. Beecher, *Experimentation in Man*, 169 J. AMER. MED. ASS. 461 (1959); Norman Howard-Jones, *Human Experimentation in Historical and Ethical Perspectives*, 16 SOC. SCI. MED. 1429, 1429-1435 (1982) (detailing history of human experimentation through Thalidomide tragedy); A.C. Ivy, *The History and Ethics of the Use of Human Subjects in Medical Experiments*, 108 SCIENCE 1, 1-2 (1948) (detailing history of human experimentation from Hippocrates to Hitler).

⁴⁸ See George J. Annas & Michael A. Grodin, *Introduction*, in THE NAZI DOCTORS, *supra* note 44, at 3, 6 (noting role of abuses in guiding thinking about research).

⁴⁹ See generally ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* 51-52 (1981) (subjects of Tuskegee Syphilis Study were recruited without their informed consent and were not subsequently informed that penicillin had become available for treatment of syphilis).

⁵⁰ See generally JAY KATZ, *EXPERIMENTATION WITH HUMAN BEINGS* 9-65 (1972) [hereinafter EXPERIMENTATION] (subjects of Jewish Chronic Disease Hospital study were chronically ill and debilitated patients injected without informed consent).

⁵¹ For a collection of essays on the Nazi Doctors' case and its impact on medical research, see generally EXPERIMENTATION, *supra* note 50, at 292-305 (collecting oral arguments and testimony); THE NAZI DOCTORS, *supra* note 44.

⁵² Doctors and soldiers with "Unit 731" dissected live prisoners, dropped "plague bombs" on entire villages, gassed mothers and children while timing their convulsions, and pickled humans in six-foot jars of formaldehyde. George J. Annas & Mi-

long history of human experimentation, and just as long a history of abusing it.⁵³

B. Is Our Unease Justified?

Maybe this historical sketch is overly tendentious, a bit overdone? After all, conscientious doctors experiment on humans under strict regulations, laws, and guidelines all the time. Clearly, most innovative therapy and research has nothing to do with the spooky deeds of Frankensteinian bogeymen or war criminals. But we should not rest too easy. Although we intuitively distinguish creative therapy from troubling experimentation—we know it when we see it—the line is not clear.⁵⁴ As Professor George Annas has argued, many “breakthrough” procedures which purported to be therapeutic triumphs—temporary artificial hearts, baboon hearts, organ transplants—were in fact blatant, experimental exploitations of desperate people.⁵⁵ What

chael A. Grodin, *Where Do We Go From Here*, in *THE NAZI DOCTORS*, *supra* note 44, at 310. The experimenters were never prosecuted because the United States granted immunity in exchange for the research data. *Id.*; see Nicholas D. Kristoff, *Japan Confronting Gruesome War Atrocity*, N.Y. TIMES, Mar. 17, 1995, at A1 (detailing research program which had prisoners deliberately infected with plague); *The Crimes of Unit 731*, N.Y. TIMES, Mar. 18, 1995, at A22 (editorializing that some of World War II's greatest atrocities were committed by Japanese Army).

⁵³ See generally Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966) (gathering data on dozens of unethical clinical experiments); David J. Rothman, *Ethics and Human Experimentation: Henry Beecher Revisited*, 317 NEW ENG. J. MED. 1195 (1987) (following up on Beecher's work and commenting on changes in experimentation and regulation since).

⁵⁴ Robert Levine has rejected the term “experimentation” altogether, along with “therapeutic research” and “nontherapeutic research.” LEVINE, *supra* note 49, at 6-8. However, in so doing, Levine loses the entirely legitimate moral and historical baggage the word “experimentation” carries. For purposes of this paper, “experimentation” denotes any practice, act, or procedure whose primary purpose is other than the benefit of the subject of that practice, act, or procedure.

Jay Katz, in his casebook, deliberately refrained from drawing “hard and fast lines between interventions for ‘the acquisition of knowledge’ or for the ‘subject's benefit’ so as to leave open the question whether the authority assigned to the participants, and any restrictions imposed upon them, in one setting should apply equally to the other.” EXPERIMENTATION, *supra* note 50, at 3.

Hans Jonas has also adopted the distinction between research done for the patient's benefit, which is permissible, and research in which the patient is exploited. See Jonas, *supra* note 22, at 242.

As Joseph Goldstein has noted, the line between permissible research and crime is not as clear as we might like to think. See CRIMINAL LAW, *supra* note 34, at 65-66 (discussing research as “defense”).

⁵⁵ See generally GEORGE J. ANNAS, *JUDGING MEDICINE* (1988) [hereinafter *JUDGING MEDICINE*].

is today standard therapy may rest on an unsightly history of overreaching.

Still, we need research; wrestling with its problems and enduring the pain of compromise may be the price we have to pay.⁵⁶ Perhaps dubious practices are justified by their necessity, their usefulness, and their contribution to the common good.⁵⁷ As Justice Frankfurter once wrote:

For society's good—if understanding be an essential need of society—inquiries into these problems, speculations about them, stimulation in others of reflection upon them, must be left as unfettered as possible.⁵⁸

But it is not enough to invoke the “common good”⁵⁹ or to say that experimentation is useful or necessary. Useful or necessary for what? Whose needs and interests justify experimentation? The subject's, society's, or the researcher's?⁶⁰ How far may we go? Will we know when we have crossed the line from solving real problems and satisfying real needs to modernity's misplaced and dangerous perfectionism?⁶¹ Will we be able to affirm per-

⁵⁶ See Calabresi, *supra* note 27, at 388-89 (noting “deep conflict” between our commitments to dignity and human life and to material progress); Louis Lasagna, *Special Subjects in Human Experimentation*, 98 DAEDALUS 449, 460-61 (1969) (noting that human experimentation is necessary for medical progress, but that some gains may only be available at a price we are unwilling to pay).

⁵⁷ In Dr. Henry Beecher's Report to the A.M.A. Council on Drugs, he observed that “it is clearly evident that human experimentation is necessary for the welfare of the race, for in medical research lies ‘a common benefit not obtainable by other means.’” Beecher, *supra* note 47, at 463. He warned, however, that in light of “the recent Hitlerian acts,” we are rightly wary of phrases like “for the good of society.” *Id.* at 463.

⁵⁸ *Sweezy v. New Hampshire*, 354 U.S. 234, 262 (1957) (Frankfurter, J., concurring).

⁵⁹ See Pope Pius XII, *An Address to the First International Congress on the Histopathology of the Nervous System*, in CRIMINAL LAW, *supra* note 34, at 91, 93 (noting limited moral claims of common good).

⁶⁰ See JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 151 (1984) (physicians claim to respond to patients' needs when planning treatment, but may really be protecting or pursuing their own); see generally RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* (1986) (describing moral principles, rights, legal theories, and concepts of informed consent); Michael D. Davidson, Note, *First Amendment Protection for Biomedical Research*, 19 ARIZ. L. REV. 893 (1977) (discussing biomedical research as protected form of expression and means of self-fulfillment for researchers).

⁶¹ See Annas, *Mengele's Birthmark*, *supra* note 45, at 18. Annas also notes, drawing on Nathaniel Hawthorne's *The Birthmark* and *Rappacini's Daughter*, the recurring “theme of the overreaching man attempting to control nature, with disastrous results” *Id.*

sonal dignity in the face of the medical ideology's tendency to objectify the human subject?⁶²

Given these worries, our unease with experimentation seems well-justified. Restraint is neither a modern nor medical virtue, but here the protection of human dignity may require it. As Professor Katz has commented:

[t]he history of experimentation with human beings also testifies to the ubiquity of human aggression, however obscured by physician-scientists' real and caring dedication to the alleviation of mankind's pain and suffering from the ravages of disease The violent authority that physicians can exercise is obscured by the social organization of the caretaking institutions within which they operate, as is the violence of judges who work within the halls of justice. Many advances in medicine might have been slower in coming had physician-investigators pursued their clinical research less aggressively by not engineering consent. Would it have been a price worth paying, even though the suffering of future patients might have remained for a while longer without relief?⁶³

Warnings about abusive experiments seem shrill and paranoid to those convinced that experimentation serves both social ends and the personal fulfillment of scientists.⁶⁴ However, hu-

⁶² See Mario Biagioli, *Science, Modernity, and the "Final Solution,"* in *PROBING THE LIMITS OF REPRESENTATION: NAZISM AND THE "FINAL SOLUTION"* 185, 187 (Saul Friedlander, ed. 1992) (noting that medicine's adoption of physical science methods led to objectification and alienation); ROBERT A. BURT, *TAKING CARE OF STRANGERS: RULE OF LAW IN DOCTOR-PATIENT RELATIONSHIPS* at 72-91 (1979) (discussing Milgram Experiments and noting science's "depersonalized methodology" and "mechanistic, objectively impersonal format which is the basic tenet of the scientific view").

⁶³ Jay Katz, *The Consent Principle of the Nuremberg Code: Its Significance Then and Now*, in *THE NAZI DOCTORS*, *supra* note 44, at 227, 238. See also CHARLES FRIED, *MEDICAL EXPERIMENTATION: PERSONAL INTEGRITY AND SOCIAL POLICY* 168 (1974) (asking whether slowing of medical progress by limiting experimentation might be price worth paying); Burt, *supra* note 10 (noting "special obligation of self-restraint" which falls on majority in democracy committed to equal respect).

⁶⁴ One researcher, recognizing that abuse may occur, points out that "despicable examples of human research are hardly typical This does not excuse the horror but it does call for perspective." Louis Lasagna, *A Researcher's Perspective*, in *HUMAN EXPERIMENTATION* 21, 23 (Robert L. Bogomolny ed., 1976) [hereinafter *HUMAN EXPERIMENTATION*]. See also Richard J. Bonnie & P. Browning Hoffman, *Regulation of Human Experimentation: A Reappraisal of Informed Consent*, in *HUMAN EXPERIMENTATION*, *supra*, at 52 (1976) (complaining that public "overreacts" to research, and is critical rather than deferential to medical and scientific judgment); Friend, *supra* note 28 (stating that Food and Drug Administration requires laboratory showing that medical device is safe to be approved).

man experimentation and its problems take us well beyond the narrow realm of medical practice:

Human experimentation cannot be analyzed in isolation ... for inherent in its dynamics are several ubiquitous forces which shape all social interaction—man's quest for knowledge and mastery, his willingness to risk human life, and his readiness to delegate authority to professionals and to rely on their judgment.⁶⁵

Our unease with research on humans therefore reflects more than a Luddite mistrust of medicine. Because of our ubiquitous curiosity, ambition, and concern, we will always want—and think we need—to “tinker,” to explore, to know,⁶⁶ and often, to exploit.

III. REGULATING HUMAN EXPERIMENTATION THROUGH CONSENT

A. *The Nuremberg Code and “Informed Consent”*

The Nuremberg Code⁶⁷ and the memory of the Nazi doctors'

⁶⁵ EXPERIMENTATION *supra* note 50, at 2; *see also* Annas & Grodin, *supra* note 48, at 7 (“The theme of human rights in human experimentation is a universal one.”).

⁶⁶ *See, e.g.*, Genesis 3:1-6 (New King James) (Adam and Eve ate from Tree of Knowledge of Good and Evil, seeking knowledge and desiring to be like God).

⁶⁷ United States v. Brandt (case no. 1), I TRIAL OF WAR CRIMINALS 3 (1949), has become known as the Medical Case because 20 of the 23 defendants were doctors and the charges related primarily to human experimentation. *See* TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL LAW NO. 10 (Vols. 1 & 2 1949) (containing trial proceedings and judgements for Nazi doctors case) [hereinafter TRIALS OF WAR]. The Nuremberg code was part of the judgment handed down in the Medical Case. *Id.* *See also* Baruch A. Brady, Book Review, *When Physicians Go Wrong*, 20 J. HEALTH POL. POL'Y & L. 503 (1995). The ten principles of the code, *infra*, outline the moral and ethical obligations that a research scientist must adhere to before beginning experimentation on human subjects. The principles are as follows:

1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be constructed; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

trial animate and permeate modern thinking about regulation of human experimentation.⁶⁸ The Code was our most morally rigorous attempt to limit human experimentation.⁶⁹ Its most memo-

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the diseases or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

reprinted in *THE NAZI DOCTORS*, *supra* note 44, at 2.

⁶⁸ See Annas & Grodin, *supra* note 48, at 3 ("[A]ll contemporary debate on human experimentation is grounded in Nuremberg ... [t]he most important historical forum for questioning the permissible limits of human experimentation."); Kathleen M. O'Connor, Comment, *OMB Involvement in FDA Drug Regulations: Regulating the Regulators*, 38 CATH. U. L. REV. 175 (1988) (indicating Nuremberg Code is reflected in modern regulations governing research). The Nuremberg Code has influenced policy and law in the area of informed consent and provided the basis for United States and foreign regulations governing the protection of human research subjects. See VEATCH, *ETHICAL PRINCIPLES IN MEDICAL EXPERIMENTATION* 21, 32-33 n.30 (A. Rivlin & P. Timpane eds., 1975). The code also influenced the court's decision in *Kaimowitz v. Michigan Dep't of Mental Health*. See *infra* notes 113-30 and accompanying text.

⁶⁹ "The Nuremberg Code was not the first code of human experimentation, nor

rable command was that, in medical research, "[t]he voluntary consent of the human subject is absolutely essential."⁷⁰ But while the Code has come to stand for "informed consent," it required more. It focused as much on the experiment itself, on the welfare of the subject, and on the conduct of the researcher as it did on the need for the subject's consent.⁷¹ Sadly, this broad focus has received relatively short shrift, and the consent principle has eclipsed the others.⁷²

The Code stands tall in memory but its influence has never lived up to its aims.⁷³ Seen by many as a product of and reaction

was it the most comprehensive ... [It is, however,] the hallmark for all subsequent discourse on the ethics of human experimentation." Michael A. Grodin, *Historical Origins of the Nuremberg Code*, in *THE NAZI DOCTORS*, *supra* note 44, at 121, 122. See generally *HUMAN EXPERIMENTATION*, *supra* note 64, at 53 (indicating Code was clearly meant to impose substantial burdens on medical research); GEORGE J. ANNAS ET AL., *INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA* 6-9 (1977) (indicating Code was most comprehensive statement on human experimentation and demanded full disclosure to subjects before their participation).

⁷⁰ See *supra* note 67 (principle 1); Leonard H. Glantz, *The Influence of the Nuremberg Code on U.S. Statutes and Regulations*, in *THE NAZI DOCTORS*, *supra* note 44, at 183 (providing overview of Nuremberg Code's influence on United States experimentation regulations).

⁷¹ For example, the code provided, "[t]he experiment should be such as to yield fruitful results for the good of society, unprocurable by other means of study, and not random and unnecessary in nature," *supra* note 68 (Principle 2); "[t]he experiment should be so designed and based on the results of animal experimentation and a knowledge of the ... disease or other problem under study that the anticipated results will justify the performance of the experiment," *id.* (Principle 3); and "[t]he experiment should be conducted only by scientifically qualified persons." *Id.* (Principle 8). See also George J. Annas & Michael A. Grodin, *Preface*, in *THE NAZI DOCTORS*, *supra* note 44 ("Discussions of human rights in human experimentation consistently begin with the Nuremberg Code."); Glantz, *supra* note 70, at 184 (indicating Code looks not only to rights of subjects, but to their welfare as well).

⁷² See Annas, *Mengele's Birthmark*, *supra* note 45, at 42 ("[The consent principle] of the Nuremberg Code, although rarely cited, became the primary justification for therapeutic experimentation. Much less attention was paid to the other nine principles.").

⁷³ "[The Code] has been criticized on a number of levels. Arguments have been put forth that suggest that the Code, in an attempt to provide for all contingencies, unduly restricts the investigator by requiring him to anticipate and provide for every situation and by demanding the impossible in some instances." Perley, et al., *The Nuremberg Code: An International Overview*, in *THE NAZI DOCTORS*, *supra* note 44, at 155 (citations omitted). The Code, by making "voluntary consent" an absolute requirement, limits the populations upon which experimentation can be conducted. *Id.* Adherence to principle 1 of the Code would effectively curtail the study of mental illness and children's diseases because children and the mentally ill do not have the legal capacity to give consent. *Id.* Other Principles of the Code have been criticized for demanding too much from the researcher. See generally *id.* "A set of 'Universal principles,' with no legal or professional authority, is successful only if researchers

to Nazi terror, the Code is often dismissed as a context-bound relic, no longer useful for today's researchers.⁷⁴ Pragmatists argue that the Code is simply too demanding, that its standards are too high for necessary research to meet,⁷⁵ and that its absolutism cannot compete with the utilitarian and impersonal ethics of modern medicine.⁷⁶ How could the Code wane to a mere symbol? It claimed, after all, roots in natural law,⁷⁷ universal values,⁷⁸ and the time-honored ethics of the medical profession.⁷⁹ In

choose to abide by them." *Id.* at 157. The Code, despite having applicability in all courts of the United States, is rarely cited. See Annas, *Mengele's Birthmark*, *supra* note 45, at 21. For a detailed discussion of the effect of the Nuremberg Code, see Panel Session, *Forty Years After the Nuremberg and Tokyo Tribunals: The Impact of the War Crimes Trials on International and National Law*, 80 AM. SOC. INT'L. L. PROC. 56 (1986).

⁷⁴ See Beeson et al., *Panel Discussion, Moral Issues in Clinical Research*, 36 YALE J. BIOLOGY & MED. 455, 464 (1964) ("[The Code] is a wonderful document to say why the war crimes were atrocities, but it is not a very good guide to clinical investigation which is done with high motives."); Katz, *supra* note 63, at 228 (indicating policymakers have viewed Code as response to isolated tragedy, unsuited to needs of modern research).

⁷⁵ "The spirit of the Nuremberg Code was not, and perhaps could not, be taken seriously. Its language was too uncompromising and too inhospitable to the advancement of science that subsequent codes reintroduced by giving physician-scientists considerable discretion in pursuing their objective." Katz, *supra* note 63, at 235.

⁷⁶ George J. Annas & Michael A. Grodin, *Where Do We Go From Here? in THE NAZI DOCTORS*, *supra* note 44, at 307, 309-10.

[T]he efforts to marginalize the Code rest primarily on a failure of physicians to take informed consent seriously and on a belief, perhaps a societal one, that when it is impossible or difficult to obtain consent, ways to get around this requirement should be found if the research is potentially important to society.

Id. See generally Annas, *Mengele's Birthmark*, *supra* note 45 (suggesting that man's inherent instinct for self-preservation is used as justification for even brutal experiments occurring after promulgation of Nuremberg Code).

⁷⁷ See Annas & Grodin, *supra* note 48, at 3 (commenting that Nuremberg Code is attempt to capture natural law standard for practical and modern business of human experimentation); ANNAS ET AL., *supra* note 69, at 6 (stating that "[t]he basis of the Code is a type of natural law reasoning.").

⁷⁸ See Ruth Macklin, *The Universality of the Nuremberg Code*, in *THE NAZI DOCTORS*, *supra* note 44, at 240, 244 (noting Code's roots in broad, Kantian principles which prohibit use of people as means to researcher's ends). The Code, in Ms. Macklin's opinion, embodied an ethical ideal, one that is universally applicable. *Id.* at 255. "All present and future research involving human subjects should comply with this ideal" *Id.* See also Grodin, *supra* note 69, at 121 (suggesting that Tribunal needed universal values grounded in history to condemn Nazis).

⁷⁹ Dr. Leo Alexander and Dr. Andrew Ivy, the prosecution's principal medical ethics witnesses, attempted to connect the Code's principles with medical ethics going as far back as the Hippocratic Oath. See Grodin, *supra* note 69, at 122-23; Katz, *supra* note 63, at 228 (noting that Tribunal erroneously believed consent

reality, the Code's drafters glossed over a long history of medical complicity in questionable experiments.⁸⁰ The Code reflected neither the practice nor the ideals of scientists, but only those of a victorious and self-congratulatory moment, and therefore, never really had a chance.

B. Regulating Experimentation After Nuremberg: The Standard Model of Informed Consent

Since Nuremberg, other codes of ethics and research, regulations, laws, and values have outpaced the Code's idealistic absolutism. The new approaches strike a compromise between the Code's idealism and the perceived need for more flexible, permissive, and perhaps realistic guidelines for research.⁸¹ For example, the Helsinki Declaration of 1964, though it superficially appears to take up the Code's torch, embodies vastly different assumptions about research and experimentation.⁸² It promotes

principles of Code had always been embraced by medical profession). The Hippocratic oath explicitly states that physicians "will follow that system of regimes which according to [their] ability and judgment, [they] consider for the benefit of [their] patients, and abstain from whatever is deleterious and mischievous." *reprinted in* Grodin, *supra* note 69, at 123 (citations omitted). The Oath speaks of obligations to patients and is silent about the subject of experimentation. *See id.* (comparing Code to Hippocratic Oath).

⁸⁰ The defense lawyers in the Nazi Doctors case emphasized that experimentation on prisoners was common in the United States and that both the United States and Great Britain had used data gleaned from Japanese wartime experiments. Macklin, *supra* note 78, at 246-47. The "medical case" transcripts can be found reprinted in *TRIALS OF WAR*, *supra* note 67.

⁸¹ *See generally* Annas & Grodin, *supra* note 76, at 307 ("[T]here has been a consistent and insistent movement away from the directness of the Code toward more flexible forms of judging the conduct of human experimentation."); Louis L. Jaffee, *Law as a System of Control*, 98 *Daedalus* 406, 420-22 (1969) (noting wide range of opinion as to importance of informed consent); Katz, *supra* note 63 (indicating modern research regulations are less rigid and demanding than Code).

⁸² The Declaration of Helsinki is more "liberal" than the Code on the issue of consent. *See* Beth Brandon, Note, *Anencephalic Infants as Organ Donors: A Question of Life or Death*, 40 *CASE W. RES. L. REV.* 781, 814 (1990). The Declaration allows consent by a legal guardian when the subject is legally incompetent. *Id.* (citations omitted). *See also* 21 *C.F.R.* § 312.120 (requiring that foreign clinical studies accepted by FDA be conducted under minimum standards of Helsinki Declaration); Hon. Sir Gerard Brennan, A.C., C.M.G., *Law in Search of a Principle*, 9 *J. CONTEMP. HEALTH L. & POLY* 259, 261 (1993) (stating that Helsinki Declaration expanded Code); Katz, *supra* note 63, at 227-28 (suggesting Nuremberg Code was "dethroned" by Helsinki Declaration); Perley et al., *supra* note 73, at 157-60 (providing in-depth comparison of Helsinki Declaration and Nuremberg Code principles); Sharon Perley, Note, *From Control Over One's Body to Control over One's Body Parts: Extending the Doctrine of Informed Consent*, 67 *N.Y.U. L. REV.* 335, 342 n.43 (1992) (indicating differences between Nuremberg Code and Helsinki Declaration).

a benign, rather than wary, view toward science and research.⁸³ Written by and for physicians, the Declaration exudes faith in the methods and goals of medical science and accepts the premise that progress requires human subjects.⁸⁴

Today, human experimentation is regulated by a crazy-quilt of hortatory codes and maxims, scattered federal laws and regulations, and most importantly, by Institutional Review Boards,⁸⁵ which provide peer review of proposed experiments.⁸⁶ "Informed

⁸³ For example, the Helsinki Declaration provides for cases where the research subject is legally incompetent to provide consent by allowing a guardian to consent. Perley et al., *supra* note 73, at 158. The greatest difference between the two codes is the Declaration's recognition and regulation of therapeutic research. *Id.* The Declaration recognized that the same ethical principles should govern when experimenting on healthy volunteers as when experimenting on those in need of care. *Id.* The Code only addressed nontherapeutic experimentation. *Id.*

⁸⁴ In 1964, at the 18th World Medical Assembly, the World Medical Association promulgated the Declaration of Helsinki. See *Declaration of Helsinki: Recommendations Guiding Doctors in Clinical Research*, reprinted in *THE NAZI DOCTORS*, *supra* note 44, at 331-39. The Declaration professes that "[i]t is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfillment of this mission." *Id.* at 331. The World Medical Association saw it as "essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity." *Id.* at 331; Perley et al., *supra* note 73, at 158; Perley, *supra* note 82, at 344.

⁸⁵ For a complete review of the structure and function of Institutional Review Boards, see, e.g., 45 C.F.R. §§ 46.107-111 (1994); 21 C.F.R. §§ 56.101-114 (1994). "IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements." 45 C.F.R. § 46.102(h).

⁸⁶ 45 C.F.R. § 46.107(a).

Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members ... to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects The IRB shall therefore include persons knowledgeable in these areas

Id. The regulatory structure controlling human experimentation and research is a vast topic, beyond the scope of this Essay. See, e.g., 45 C.F.R. §§ 46.101-409 (regulating research involving human subjects through use of IRB's); 21 C.F.R. §§ 50.1-48 (regulating clinical investigations regulated by F.D.A.); 21 C.F.R. §§ 312.1-120 (promulgating procedures and regulations for use of investigational new drugs). See generally DENNIS M. MALONEY, PROTECTION OF HUMAN RESEARCH SUBJECTS (1984) (providing comprehensive presentation of regulations governing human experimentation, designed to help researchers); William J. Curran, *Governmental Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies*, 98 DAEDALUS 542 (1969) (overviewing both Food and Drug Administration and National Institutes of Health regulations pertaining to medical research); Glantz, *supra* note 70, at 183-200 (noting that Code is not law, and has had little influence on law in United States); LEVINE, *supra* note 49, at 69-115, 207-

consent" is still the touchstone, but modern regulations and procedures tolerate and expect deviations from this ideal.⁸⁷ Thus, when addressing human experimentation—and they rarely do—courts occasionally mention the Code, but generally apply and enforce the more flexible informed consent requirements of later regulations.⁸⁸

The legal doctrine of informed consent as it has developed is quite different from the dignity-based commitment to self-determination animating the Nuremberg Code.⁸⁹ The most important feature of today's regulatory regime is that it focuses on

43 (discussing informed consent in general and discussing function and role of IRB).

⁸⁷ See, e.g., 21 C.F.R. § 50.23 (listing "exceptions from general requirements" of informed consent); 45 C.F.R. §§ 46.116(c), (d) (describing situations where informed consent is not required).

⁸⁸ See generally *Hinkie v. United States*, 715 F.2d 96 (3d. Cir. 1983) (barring claim that soldier's widow's miscarriages and son's birth defects were caused by soldier's radiation exposure; *Feres* doctrine bars claims incident to active duty), *cert. denied*, 465 U.S. 1023 (1984); *Jaffee v. United States*, 663 F.2d 1226 (3d Cir. 1981) (dissenting judge cited Nuremberg Code as justification for soldier's claim, although court held that United States was immune from claim that Government's nuclear explosion experiment caused soldier's death), *cert. denied*, 456 U.S. 972 (1982); *Karp v. Cooley*, 493 F.2d 408, 423-24 (5th Cir.) (denying wrongful death claim brought by widow of recipient of first mechanical heart, finding "human experimentation" evidence irrelevant because heart had therapeutic value), *cert. denied*, 419 U.S. 845 (1974); *Begay v. United States*, 591 F. Supp. 991, 998 (D. Ariz. 1984) (distinguishing data gathering from experimentation in denying Native American's tort claim for injuries allegedly caused by exposure to uranium radiation), *aff'd*, 768 F.2d 1059 (9th Cir. 1985); *Strunk v. Strunk*, 445 S.W.2d 145 (Ky. Ct. App. 1969) (authorizing removal of kidney from mentally retarded adult for transplant to brother after receiving consent from guardian). "Apparently because of my indelible recollection of a government which, to the everlasting shame of its citizens, embarked on a program of genocide and experimentation with human bodies I have been more troubled in reaching a decision in this case than in any other." *Id.* at 149 (Steinfeld, J., dissenting); *Annas, Mengele's Birthmark*, *supra* note 45 (providing review of United States court decisions citing Nuremberg Code).

But see *Washington v. Harper*, 494 U.S. 210, 237 n.2 (1990) (Stevens, J., dissenting) (noting Justice O'Connor's opinion in *United States v. Stanley*, *infra*, which stated that Due Process guarantees at least compensation for violations of consent principle of Nuremberg Code); *United States v. Stanley*, 483 U.S. 669, 686-90 (1987) (Brennan, J., dissenting) (citing Nuremberg Code and decrying Army secret LSD experiments); *Whitlock v. Duke Univ.*, 637 F. Supp. 1463 (M.D.N.C. 1986) (declining relief sought by subject suffering organic brain damage after applying Nuremberg standard for consent), *aff'd*, 829 F.2d 1340 (4th Cir. 1987); *Jaffee*, 663 F.2d at 1249 (Gibbons, J., dissenting) (noting that radiation experiments violated Nuremberg Code and other principles of international law).

⁸⁹ See Glantz, *supra* note 70, at 189-91 (criticizing version of informed consent in federal regulations for departing from Code's strict requirements); Jay Katz, *Informed Consent: A Fairy Tale? Law's Vision*, 39 U. PITT. L. REV. 137, 143-64 (1977) [hereinafter Katz, *Informed Consent*] (tracing development of informed consent doctrine since Nuremberg).

the subject's state of mind more than on the experiment itself.⁹⁰ What is referred to here as the "Standard Model" of informed consent is this subjectively oriented informed consent in the context of peer review. In practice, research peers have proven insufficiently critical when evaluating proposed experiments.⁹¹ In addition, the informed consent "requirement" is viewed as a chore and a ritual, an impersonal incantation, a hurried signing of papers.⁹² We know this is true, yet we cherish the myth of informed consent, skating over its lack of real content or impact.⁹³ But because the Standard Model is a subterfuge aimed more at easing our consciences than at protecting research subjects,⁹⁴ it fails both as a necessary condition for proposed experiments⁹⁵ and as a justification for them.

IV. THE STANDARD MODEL IN ACTION: INFORMED CONSENT IN HARD CASES

So far, this discussion has had two points. First, troublesome and abusive experiments on human subjects occur more often than we realize or admit.⁹⁶ Second, these unsettling cases arise despite, or because of, a loose regulatory regime that delegates the duty of reviewing experiments to a peer-review board

⁹⁰ See Joseph Goldstein, *For Harold Lasswell: Some Reflections on Human Dignity, Entrapment, Informed Consent, and the Plea Bargain*, 84 YALE L. J. 683, 690-91 (1975) (stating that informed consent is used to "emphasize a patient's or subject's actual state of mind, knowledge or understanding ... rather than to emphasize ... the conduct required of the therapist or experimenter.").

⁹¹ "IRB's as currently constituted do not protect research subjects but rather protect the institution and the institution's investigator." Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 40 (1993) [hereinafter Katz, *Human Experimentation*] (citations omitted). The objectivity of IRB members may be suspect because of built-in conflicts of interest. *Id.* at 17, 32-33.

⁹² See generally Katz, *Informed Consent*, *supra* note 89 (calling law of informed consent a fairy tale myth).

⁹³ *Id.* at 137-38 (noting our "childlike conviction" that implied consent has meaning and that we "go to great lengths in denying that the emperor has no clothes").

⁹⁴ See Calabresi, *supra* note 27, at 389-90 (noting "beauty" of decision-making devices which hide and depersonalize our decisions to exploit others, and which allow us to continue to profess commitments to life as sacred).

⁹⁵ See O'Connor, *supra* note 68, at 178 (indicating that situations arise which create pressure, resulting in activities without compliance with informed consent); see also *supra* note 87 (citing regulations which provide exceptions to informed consent requirement).

⁹⁶ "[T]he actions of the Nazi physicians were not isolated instances of 'crimes against humanity' Similar transgressions occurred prior to the Nuremberg trials and continue to occur, though because they are less dramatic their existence is more likely to be denied." JAY KATZ, *EXPERIMENTATION WITH HUMAN BEINGS* 283 (1972).

and unenthusiastically requires research subjects' informed consent.⁹⁷

Admittedly, in most cases, research experiments using human subjects are relatively innocuous. Consent is easily obtained and its validity unquestioned. The risks are low, the goals are clear, and the subjects are everyday people in nonthreatening situations. At the other end of the spectrum are the Jewish Chronic Disease Hospital experiments,⁹⁸ the Tuskegee Syphilis Study,⁹⁹ and the Nazi doctors' case.¹⁰⁰ These Doctors' cases are easy to analyze and condemn, even for the most ardent research supporters, because subjects were deceived and coerced. In more difficult cases, however, even when it appears that the subject consented freely, an uneasy sense remains.¹⁰¹ Sometimes the subject does not, or cannot, consent, but it is imperative that the experiment nonetheless go forward.¹⁰² How does the Standard Model of informed consent handle such cases?

The Standard Model regulates experiments by requiring the subjects' informed consent. Comparatively little attention is given to the nature of the experiment itself—apart from its riskiness—or to the researcher's goals and intentions.¹⁰³ Under

⁹⁷ See *supra* note 88 (citing case law addressing claimed unethical experimentation on human subjects); see also *Barrett v. United States*, 660 F. Supp. 1291 (S.D.N.Y. 1987) (holding that United States negligently caused death by using inadequately tested drug in human experimentation); *Molsbergen v. United States*, 757 F.2d 1016 (9th Cir.) (holding widow's claim for wrongful death of husband due to exposure to radiation from Government experimentation was not barred), *cert. dismissed*, 473 U.S. 934 (1985); *Clay v. Martin*, 509 F.2d 109 (2d Cir. 1975) (allowing prisoner's claim for alleged inhumane treatment under medical experimentation).

⁹⁸ See *supra* note 50.

⁹⁹ See *supra* note 49.

¹⁰⁰ See *supra* note 51.

¹⁰¹ See *Whitlock v. Duke Univ.*, 829 F.2d 1340, 1343 (1987) (labeling risk of experiment which increased permanent brain damage as unforeseeable, therefore justifying university's failure to refer to it on consent form).

¹⁰² This may occur with mental patients, the developmentally disabled, Alzheimer's patients, and in extreme medical emergencies. See Philip M. Bein, *Surrogate Consent & the Incompetent Experimental Subject*, 46 FOOD DRUG COSM L.J. 739, 739 (1991); see *supra*, note 87, for regulatory exceptions to informed consent.

¹⁰³ Federal regulations define research as "a systematic investigation ... designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy." 45 C.F.R. § 46.102(d) It appears that if research doesn't satisfy this definition, the researcher can avoid these regulations. Additionally, the IRB is directed to review only the informed consent form, the risk involved, and general research activities before approving or disapproving the research program. See 45 C.F.R. § 46.109. The regulation makes no mention of requiring IRB investigation of the goals and intentions of the researcher.

the Standard Model, concern may be triggered by some characteristic of the subject (age, health, mental capabilities) or by the experiment's location (prison, hospital, university). These characteristics and locations, however, relate less to whether the researcher's plan is itself ethical, than whether the subject's consent was really given, or was truly informed.¹⁰⁴ When experiments are prohibited, it is due to the quality, or lack thereof, of the consent given, not the propriety of the experiment itself.¹⁰⁵ In these situations, whatever it is that gives the subject's consent its justificatory power—the mysterious indicia of autonomy worth respecting—is deemed lacking. To illustrate this dynamic at work, I review below the operation of the Standard Model in three paradigmatically hard cases.¹⁰⁶

A. Prisoners

Prisoners have long been conveniently immobile, docile, and hence ideal subjects for research and experimentation: "[P]risons are almost ideal places to conduct research. Life is routine and subject to few variations. The population is relatively stable The imposition of experimental procedures that might inconvenience free-living subjects is not a burden on prisoners. It is also less expensive"¹⁰⁷ Accordingly, experimentation on prisoners is carefully scrutinized under the Standard Model.¹⁰⁸ The Department of Health and Human Services warns that "prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced

Id.

¹⁰⁴ Age, health, and mental capabilities address a human subject's ability to give legally competent consent. See Perley et al., *supra* note 73, at 155 (indicating some classes of human subjects lack legal capacity to give consent). The location of the research project presents issues of "captive exploitation" of the subjects involved. See Glantz, *supra* note 70, at 191-92 (discussing problems with research conducted at prisons on prisoners). Captivity undercuts the voluntariness of the consent given.

Id.

¹⁰⁵ See *supra* note 104.

¹⁰⁶ See generally Glantz, *supra* note 70, at 191-94 (discussing problems with research on prisoners and children); Lasagna, *supra* note 56 (reviewing problems associated with use of prisoners, children, and mentally ill in human experimentation).

¹⁰⁷ ANNAS ET AL., *supra* note 69, at 103.

¹⁰⁸ See generally *id.* at 103-38 (discussing problem of voluntariness with prisoners); Lasagna, *supra* note 56, at 449-55 (discussing issues surrounding prisoners as research subjects); LEVINE, *supra* note 49, at 181-96 (highlighting informed consent concerns when prisoners are used in experimentation); MALONEY, *supra* note 86, at 343-60.

decision whether or not to participate as subjects in research."¹⁰⁹

This concern about prisoners' capacity to choose goes to the heart of the Nuremberg Code, which took its shape precisely because the Code's drafters were so appalled at experiments conducted under duress.¹¹⁰ Therefore, the scope of prisoner research eligible for federal funding is limited to, among other things, the study of possible causes of incarceration and criminal behavior, of prisons as institutions, and of conditions affecting prisoners as a class.¹¹¹ It is important to note the underlying motivation for these regulations. Prisoners are presumed less able to choose freely because they supposedly suffer from false consciousness about their own best interests, *not* because researchers simply should not be experimenting on the most vulnerable among us.¹¹²

The best known prison research case is *Kaimowitz v. Michigan Department of Mental Health*.¹¹³ John Doe had been committed to a state hospital as a criminal sexual psychopath.¹¹⁴ After 17 years of hospitalization, he was designated a suitable research subject for a study of "uncontrollable aggression."¹¹⁵ The research was designed to compare the effects on male hormone flow of a psychosurgical procedure with those of a particular

¹⁰⁹ 45 C.F.R. § 46.302.

¹¹⁰ As General Taylor said, "[i]n the tyranny that was Nazi Germany, no one could give such a consent to the medical agents of the state; everyone lived in fear and acted under duress." Telford Taylor, *Opening Statement of the Prosecution, December 9, 1946*, in *THE NAZI DOCTORS*, *supra* note 44, at 89. Principle 1 of the Nuremberg Code stated, "the person involved should have legal capacity to give consent; [they] should be so situated as to be able to exercise free power of choice without ... duress." *Supra* note 68 (principle 1 of Code).

¹¹¹ 45 C.F.R. § 46.306(a)(2)(i-iii) (1994). The Department of Health and Human Services' regulations also call for special Institutional Review Boards with additional duties, including ensuring that the risks of the experiment are commensurate with risks which would be accepted by nonprisoners, and that the possible advantages of participating in the experiment are not so great as to impair the prisoners' ability to decide in the "limited choice environment of the prison" 45 C.F.R. § 46.304-305 (1994).

¹¹² See ANNAS ET AL., *supra* note 69, at 103-38 (discussing how research with prisoners presents "problem of voluntariness"); Grodin, *supra* note 69, at 138 (discussing federal regulations addressing research using prisoners).

¹¹³ Civil No. 73-19434-AW (Cir. Ct. Wayne County, Mich., July 10, 1973), summarized in 42 U.S.L.W. 2063 (July 31, 1973), reported in 1 MENTAL DISABILITY L. REP. 147 (1976). See generally John R. Mason, Note, *Kaimowitz v. Department of Mental Health: A Right to Be Free From Experimental Psychosurgery?*, 54 B.U. L. REV. 301 (1974) (discussing moral and legal dilemmas involved with psychosurgery when subject is mental patient).

¹¹⁴ *Kaimowitz*, 1 MENTAL DISABILITY L. REP. at 147.

¹¹⁵ *Id.*

drug.¹¹⁶ Doe was the only known appropriate candidate for the surgery.¹¹⁷ He signed an informed consent form; his parents' consent was also obtained.¹¹⁸ A "Scientific Review Committee" and a "Human Rights Review Committee" reviewed and approved the proposed experiment.¹¹⁹

The Michigan court, after granting a writ of *habeas corpus*, decided the case despite a burst of publicity which stymied the experiment.¹²⁰ The court noted the uncertainty and risk surrounding psychosurgery, and insisted that "[p]sychosurgery should never be undertaken upon involuntarily committed populations, when there is a high-risk low-benefits ratio as demonstrated in this case. *This is because of the impossibility of obtaining truly informed consent from such populations*"¹²¹ The court added that "there must be close scrutiny of the adequacy of the consent when an experiment ... is dangerous, intrusive, irreversible, and of uncertain benefit to the patient and society."¹²² The court also discussed the Nuremberg Code's informed consent requirement, the effects of institutionalization on prisoners' decision-making capabilities,¹²³ and its concerns about inequalities

¹¹⁶ *Id.* On the ethical issues posed by psychosurgery, see ANNAS ET AL., *supra* note 109, at 215-55 (defining psychosurgery as "any procedure that destroys brain tissue for the primary purpose of modifying behavior."). Psychosurgery may be enjoying a renaissance of sorts. See, e.g., Michael W. Miller, *Brain Surgery is Back in a Limited Way to Treat Mental Ills*, WALL ST. J., Dec. 1, 1994, at A1.

¹¹⁷ *Kaimowitz*, 1 MENTAL DISABILITY L. REP. at 147.

¹¹⁸ *Id.*

¹¹⁹ *Id.* See Burt, *supra* note 47, at 26-27 (describing committees involved in Kaimowitz Experiment).

¹²⁰ Kaimowitz became aware of the experimental work about to be performed on John Doe and made his concern known to the Detroit Free Press. *Kaimowitz*, 1 MENTAL DISABILITY L. REP. at 147. A substantial amount of media coverage ensued and the case was filed shortly thereafter. *Id.* As a result of the coverage and the pending legal action, funding for the experiment was stopped. *Id.* Shortly thereafter, the research doctors dropped the planned experiment. *Id.* The lawsuit continued after the court determined that the case was not moot. *Id.*

¹²¹ *Kaimowitz*, 1 MENTAL DISABILITY L. REP. at 148 (emphasis added).

¹²² *Id.* at 149 (citations omitted). It is ironic that the court found that the novelty of psychosurgery weighed against its permissibility. As Robert Burt has commented, prison is itself "experimental" in that its deleterious effects have not been adequately researched, nor its benefits established. Burt, *supra* note 47, at 31. See generally MICHEL FOUCAULT, *DISCIPLINE & PUNISH: THE BIRTH OF THE PRISON* (Alan Sheridan trans., 1977) (discussing prisons and symbolic power of punishment).

¹²³ *Kaimowitz*, 1 MENTAL DISABILITY L. REP. at 150-51; see also ANNAS ET AL., *supra* note 69, at 240-41 (discussing recommendation for insuring informed consent in psychosurgery cases via IRB hearings on subject's ability to consent to procedure).

in bargaining power.¹²⁴

Kaimowitz is dramatic, but not unique.¹²⁵ The case illustrates a difficulty with using informed consent as the moral touchstone for research on prisoners.¹²⁶ The insidiously pervasive message of modern penology, which may unfortunately justify experimentation, is that prisoners need reform, reshaping and alteration.¹²⁷ Prisoners may be conditioned by prison to see themselves as "in need of repair."¹²⁸ Consequently, prisoners might well decide that a dangerous "reformatory" experimental treatment is in their best interests and then decide, quite rationally, to take a high-risk gamble on freedom. A prisoner like Doe who consents to psychosurgery may have fallen into false consciousness or he may shrewdly have decided that a chance at freedom is worth a scalpel to the head. The *Kaimowitz* court claimed to protect Doe's best interests¹²⁹ by forbidding experiments in prison, but Doe might well have answered, "easy for you to say! It's my funeral, and I want out!" Who are we to say no? Alternatively, a prisoner might simply want to give something back to society, to redeem, atone, and reconcile. Why should he be stopped?¹³⁰ The Standard Model provides no an-

¹²⁴ *Kaimowitz*, 1 MENTAL DISABILITY L. REP. at 149-50.

¹²⁵ See, e.g., *Bailey v. Lally*, 481 F. Supp. 203 (D. Md. 1979) (holding that prison conditions did not render prisoners' participation involuntary); *Washington v. Harper*, 494 U.S. 210, 221-23 (1990) (defining right of prisoner to avoid unwanted administration of antipsychotic drug).

¹²⁶ The *Kaimowitz* decision held that adequate informed consent can be obtained from a mental patient if the procedure was an accepted medical procedure. *Kaimowitz*, 1 MENTAL DISABILITY L. REP. at 153. However, in *Kaimowitz*, the psychosurgical procedure was determined to be experimental, thereby invalidating the informed consent given. *Id.* The *Kaimowitz* court does not give adequate consideration to other issues surrounding informed consent from the institutionalized. See generally ANNAS ET AL., *supra* note 69 at 103-193 (discussing issues surrounding experimentation on institutionalized persons).

¹²⁷ See generally NICOLA LACEY, *STATE PUNISHMENT: POLITICAL PRINCIPLES AND COMMUNITY VALUES* (1994) (providing overview of goals of criminal punishment).

¹²⁸ Burt, *supra* note 47, at 30 (citing Doe's situation in *Kaimowitz* as illustrative of how institutionalized persons come to view themselves as desperately needing help at any cost).

¹²⁹ Guido Calabresi once remarked to the author that the real issue in *Kaimowitz* was the court's—and our—unwillingness to face the fact that prison life was so bad that persons would risk even psychosurgery to get out. As Robert Burt noted, "[b]y withholding the possibility of legally consented psychosurgery from John Doe, we are thus protecting ourselves more than him." *Id.* at 34.

¹³⁰ One critic of excessive "protection" for prisoners notes that "opponents of prisoner research seem supremely indifferent to readily available opinions of many prisoner subjects that 'protection' from the chance to be a subject is not a boon, but a

swers.

B. The Terminally Ill

"[T]he most used and useful of all experimental subjects is the patient with disease."¹³¹ For example, John Russell, suffering from lung problems, was the recipient of the first lung transplant.¹³² In addition to enduring his life threatening illness, Russell was serving a life sentence for murder, making him doubly vulnerable.¹³³ Russell succumbed to his illness despite the lung transplant.¹³⁴ Boyd Rush, the first chimpanzee heart recipient, was a poor deaf-mute, and did not consent to the transplant when he arrived at the hospital unconscious and dying.¹³⁵ Jefferson Davis, a poor black man dying of glomerulonephritis, agreed to a chimpanzee kidney transplant after doctors told him he would otherwise die.¹³⁶ He died anyway, two months later.¹³⁷ In

further limiting of the convict's options." HUMAN EXPERIMENTATION, *supra* note 64, at 21; see also Lasagna, *supra* note 56, at 454-55 (questioning whether prisoners' rights are protected by preventing them from volunteering for experiments). In a more provocative vein, Robert Burt asks why, if we are willing to incarcerate some, and to experiment on some, we do not let prisoners choose between the two socially sanctioned options? Burt, *supra* note 47, at 27; Bailey v. Lally, 481 F. Supp. 203, 220 (D. Maryland 1979) ("[Plaintiff's cases] do not address the question of the constitutionality of offering a choice to an inmate to participate in a worthwhile but unpleasant activity which may be more attractive to him because of his environment."); Edward A. Fitzgerald, *Chemical Castration: MPA Treatment of the Sexual Offender*, 18 AM. J. CRIM. L. 1, 21 (1990) (arguing that prisoner participation in castration experiments should be valid despite their personal interests in relieving boredom, earning money, improving living conditions, and getting released).

¹³¹ George J. Annas, *The Hospital: A Human Rights Wasteland*, 1 CIV. LIB. REV. 9, 15 (1974) [hereinafter Annas, *The Hospital*] (quoting leading medical commentator Franz Ingelfinger). See generally Henry K. Beecher, M.D., *Ethical Problems Created by the Hopelessly Unconscious Patient*, 278 NEW ENG. J. MED. 1425, 1430 (1968) (noting importance of tissues and organs of terminally ill for research and experimentation purposes); EXPERIMENTATION, *supra* note 50, at 1053-108 (reporting case studies of dying patients as research subjects and organ donors); Lasagna, *supra* note 56, at 455-57 (noting scientific problems associated with use of dying research subjects).

¹³² Dr. James D. Hardy performed the world's first lung transplant on John Richard Russell in 1963. *Lung Recipient Leaves Hospital*, UPI, Mar. 12, 1987 available in LEXIS, NEXIS Library, UPI File.

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ Dr. James D. Hardy performed the surgery after Rush's sister signed the consent form indicating a "suitable heart" (emphasis supplied) would be found. Apparently Dr. Hardy interpreted "suitable heart" broadly enough to justify the use of a chimpanzee heart. See ANNAS ET AL., *supra* note 69, at 15-16.

¹³⁶ *Id.* at 15.

¹³⁷ EXPERIMENTATION, *supra* note 50.

all these cases, the person's "dying status was used against [him] as the primary justification for the experiment."¹³⁸ Additionally, in all of these cases, the ritual of obtaining consent was implemented more as a formality than an opportunity for choice or a vehicle for empowerment.¹³⁹

As with prisoners, experimentation with terminally or grievously ill patients distorts the Standard Model.¹⁴⁰ Like children or the mentally handicapped, dying persons are often thought of as incapable of making informed decisions;¹⁴¹ and like prisoners, they are viewed as not "really" free, but instead, captive to the course of their disease and therefore under duress.¹⁴² Even when these patients are lucid, we fear their assessment of an experiment's benefits and risks may be skewed; we worry they might submit to quackery in a hopeless and desperate attempt to beat the inevitable.¹⁴³ We also worry that the dying may, having abandoned all hope, submit to immoral experiments out of misplaced or entirely genuine altruism.¹⁴⁴ Finally, we fear that we

¹³⁸ George J. Annas, *Baby Fae: The 'Anything Goes' School of Human Experimentation*, in JUDGING MEDICINE, *supra* note 56, at 384-85 [hereinafter Annas, *Baby Fae*].

¹³⁹ See *supra* notes 107-38 and *infra* notes 140-74 (discussing consent issues when research subjects are prisoners, terminally ill, or children).

¹⁴⁰ On a related issue, see Robert L. Schwartz, *Informed Consent to Participation in Medical Research Employing Elderly Human Subjects*, 1 J. CONTEMP. HEALTH L. & POL'Y 115 (1985).

The attributes found more frequently among elderly research subjects than among younger subjects—cognitive and emotional impairment, impaired vision and hearing, difficulty in resisting coercion, dependence on family and health care providers, acceptance of non-mainstream values, institutionalization in nursing homes—require that the doctrine of competent, voluntary, informed consent be especially carefully applied in research employing elderly subjects.

Id. at 130.

¹⁴¹ See Jacquelyn A. Beatty, Comment, *Artificial Nutrition and the Terminally Ill: How Should Washington Decide?*, 61 WASH. L. REV. 419, 423 (1986) (noting that legal and medical authorities advocate greater emotional comfort and dignity and less aggressive medical intervention for dying patients).

¹⁴² See EXPERIMENTATION, *supra* note 50, at 1053; *Compassion in Dying v. State of Washington*, 49 F.3d 586, 592 (9th Cir. 1996) (declaring state has interest in "not subjecting the elderly and even the not-elderly but infirm to psychological pressure to consent to their own deaths."), *reversed*, 79 F.3d 790 (9th Cir. 1996) (*en banc*).

¹⁴³ But see Delaney, *supra* note 44, at 418-19 (advocating access to experimental therapies for AIDS patients).

¹⁴⁴ One commentator, writing about the Jewish Chronic Disease Hospital Case, suggested that dying patients might volunteer for experiments, thinking, "I know it is too late for me. Maybe this will help somebody else." Earl Ubell, *Injecting Cancer Cells - The Case for the Defense*, N.Y. HERALD TRIB. 29, col. 5 (Jan. 26, 1964), *re-*

may be tempted to exploit these subjects' despair, incapacity, or altruism, and to railroad through experiments which might not otherwise pass ethical muster.

Given these concerns, how does the Standard Model treat terminally ill research subjects? As with Doe in *Kaimowitz*,¹⁴⁵ we often use the patient's desperation to disempower his consent. His terror of death is a surrogate for duress, and so his consent is not voluntary. On the other hand, if *we* feel that the experiment is useful or necessary, and not that demeaning or dangerous, we might choose not to look behind the act of consent. After all, if we are too critical of consent once given, we lose valuable research resources. We cannot afford to be too scrupulous.

Consider here the Jewish Chronic Disease Hospital case,¹⁴⁶ in which three doctors injected dying and uninformed patients with live cancer cells.¹⁴⁷ The experiment was completely unrelated to the patients' normal medical programs, violating what one writer has called the "fundamental privilege of the sick."¹⁴⁸ During the resulting controversy, the plaintiffs objected that actual consent should have been, but was not, given by the patients.¹⁴⁹ They did not claim that the experiment itself was unethical.¹⁵⁰ But what if the patients *had* consented? Should they have been treated like lucid altruists, eager to do their share in the fight against cancer, or like the desperate and grasping patients whose volition we question? Or, should we place all such patients outside the realm of available subjects and refuse to use their misfortune for our own and others' bene-

printed in EXPERIMENTATION, *supra* note 50, at 39-40.

¹⁴⁵ See generally Mason, *supra* note 113, at 319 (explaining that institutionalized individuals are particularly vulnerable to pressures that may impair judgment and cannot freely choose experimental psychosurgery).

¹⁴⁶ *Hyman v. Jewish Chronic Disease Hosp.*, 251 N.Y.S.2d 818 (2d Dep't 1964), *rev'd* 15 N.Y.2d 317 (N.Y. 1965); see also EXPERIMENTATION, *supra* note 50, at 9-65 (analyzing research policies, administration, and consequences of *Jewish Chronic Disease Hospital* case).

¹⁴⁷ *Jewish Chronic Disease Hosp.*, 15 N.Y.2d at 318-19.

¹⁴⁸ Jonas, *supra* note 22, at 238. "The expiring moments should be watched over with piety and be safe from exploitation." *Id.* at 245.

¹⁴⁹ See *Jewish Chronic Disease Hosp.*, 15 N.Y.2d at 319-20.

¹⁵⁰ See EXPERIMENTATION, *supra* note 50, at 60-3 (reprinting Hospital Board of Regents' Discipline Committee Recommendations indicating that nature of particular experiment was unethical separate and apart from issue of whether consent was properly given). There was medical consensus that the experiments were not in fact harmful to the patients. *Id.* See also Ubell, *supra* note 144, at 39 (noting small likelihood of successfully transplanting cancer from one human being to another and trumpeting benefits of such experiments in developing cancer vaccine).

fit?¹⁵¹

C. Children

The use of children poses even thornier problems for research.¹⁵² We need to experiment on children; their problems and illnesses are often *sui generis* and can only be solved through experiments on them. However, the Standard Model assumes children cannot give adequate consent, and so it gives in to necessity,¹⁵³ though the Nuremberg Code insisted that the subject's consent was essential.¹⁵⁴ Because children cannot, by definition, give consent, we settle for less.¹⁵⁵ In addition, because children are a necessary and unique research class, we are forced to face the steely utilitarian calculus that hides beneath the Standard Model's veneer of respect for persons.¹⁵⁶

The Standard Model requires *someone's* consent, and parents are the most obvious candidates.¹⁵⁷ However, even parents

¹⁵¹ See Jonas, *supra* note 22, at 238-39 (insisting that sick subjects never be used except for own benefit).

¹⁵² See generally ANNAS, ET AL., *supra* note 69, at 63-101 (addressing whether children are capable of giving and understanding consent and parent's legal capacity to consent for their children); CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS, AND THE LAW (Michael A. Grodin & Leonard H. Glantz, eds. 1994) (collection of essays on difficult questions posed by experimentation and research on children); LaSagna, *supra* note 56, at 457-58 (discussing controversial issues surrounding use of children in experiments); See also 45 C.F.R. §§ 46.401-409 (1994) ("Additional Protection for Children Involved as Research Subjects"). A recent news item noted that the Food and Drug Administration does not require drug makers to test over-the-counter drugs for children "before putting them on the market, in part because of ethical questions." Elyse Tanouye, *Toddlers Taking Many Drugs, Mostly Untested*, WALL ST. J., Oct. 5, 1994, at B1.

¹⁵³ "So spake the Fiend, and with necessity, The tyrant's plea, excused his devilish deeds." Regina v. Dudley & Stephens, 14 Q.B. 273, 288 (1884) (quoting J. MILTON, PARADISE LOST, BK.IV, lines 393-94).

¹⁵⁴ See Barry Kellman, *Judicial Abdication of Military Tort Accountability: But Who is to Guard the Guards Themselves?*, 1989 DUKE L.J. 1597, 1621 (1989) (interpreting Nuremberg Code as mandating voluntary consent prior to experimentation).

¹⁵⁵ Some do argue, however, that because children cannot give rational consent, they might be excluded from research altogether. See Frederick S. Carney, *A Moral Analysis of Human Experimentation*, in HUMAN EXPERIMENTATION, *supra* note 64, at 132, 145.

¹⁵⁶ See ANNAS ET AL., *supra* note 69, at 63-64 (indicating that beneficial nature of research on children does not establish its legality).

¹⁵⁷ In some circumstances, federal regulations waive the parental consent requirement. But see 45 C.F.R. § 46.408(c) (1994) (waiving consent requirements where parental permission is "not a reasonable requirement to protect the subjects," as in abuse and neglect circumstances).

might not be able to isolate and protect an individual child's safety and dignity, especially when another child is thrown into the equation.¹⁵⁸ The same considerations that call into question whether a prisoner's consent was voluntary or informed might undermine a desperate parent's consent as well.

In the famous "Baby Fae" case, a poor and dying child was given an experimental baboon heart transplant.¹⁵⁹ Although a committee, appointed by the National Institutes of Health, reviewed the experiment and the child's mother consented,¹⁶⁰ the transplant remains a distressing example of conceit and exploitation.¹⁶¹ The mother was most certainly influenced by her child's desperate situation. Even if her consent was freely and knowingly given, the question perhaps should never have been asked.

In *Hart v. Brown*,¹⁶² doctors preparing to transplant a kidney from one identical twin to another sought declaratory judgment that the twins' parents had the right to consent to the procedure.¹⁶³ The court observed, following the Standard Model, that children, of course, do "not have the legal capacity to consent."¹⁶⁴ The court then described the urgent need for the procedure, the relative lack of risk to the donor, and the prospects for success.¹⁶⁵ Importantly, the court insisted that such a transplant was not experimental, but rather "medically accepted therapy."¹⁶⁶ Given the circumstances, the court held that the parents could consent

¹⁵⁸ For example, in *Hart v. Brown*, 289 A.2d 386 (Conn. Super. Ct. 1972), the state reviewed the decision of parents to consent to elective kidney surgery on one child in order to prevent the death of another child. See Joseph Goldstein, *Medical Care for the Child at Risk: On State Supervention of Parental Autonomy*, 86 YALE L.J. 645, 668-70 (1977). See also ANNAS ET AL., *supra* note 69, at 86 (discussing transplant cases where parents might view healthy child as means to end of curing sick child and distorted rate of parent as protector of donor child).

¹⁵⁹ See Lawrence K. Altman, *Survival Record is Set by Heart Implant Baby*, N.Y. TIMES, Oct. 31, 1984, at 18.

¹⁶⁰ See Harry Nelson, *Baby Fae's Kin Knew of Risks, U.S. Study Says*, L.A. TIMES, March 15, 1985, at 3.

¹⁶¹ See generally Annas, *Baby Fae*, *supra* note 140, at 384-90.

¹⁶² 289 A.2d 386 (Conn. Super. Ct. 1972).

¹⁶³ *Id.* at 387.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.* at 388-90.

¹⁶⁶ *Id.* at 390. The court also noted, however, that there was authority that parents can consent to nontherapeutic operations on their children as well, citing *Bonner v. Moran*, 126 F.2d 121, 123 (D.C. Cir. 1941) (validating parental consent to transfer of skin from a 15-year old son to his burned cousin).

to the transplant.¹⁶⁷ Although the court emphasized that the parents had given long and careful thought to the matter,¹⁶⁸ the focus of the decision was on the procedure itself, its relative safety, and the need for the kidney.¹⁶⁹ Since the kidney was needed, the parents' consent would suffice.¹⁷⁰

With children, therefore, the Standard Model of informed consent is stymied. Faced with a subject who presumably cannot consent, the Standard Model looks for someone else's consent. This is a big jump. After all, informed consent supposedly legitimates and justifies experimentation because that consent protects autonomy; but how can it when someone else is providing the consent? "Proxy consent" is an oxymoron if consent truly aims at protecting self-autonomy and self-determination.¹⁷¹ Through proxy consent, the subject is labelled a morally impotent agent—less than autonomous. This is because the unspoken, but persistent, utilitarianism which underlies so much of our thinking about experimentation requires us to find some way to permit needed experiments while still giving lip-service to our values. It is not that we are lying in these cases; we are genuinely torn.¹⁷² We are utilitarian *and* we are committed to human dignity; when we are forced to compromise, we need to hide the tradeoff and to profess continued respect for the value that lost out.¹⁷³ The Standard Model reflects the tension inevitably produced by this tragic compromise.¹⁷⁴

¹⁶⁷ *Hart*, 289 A.2d at 391.

¹⁶⁸ *Id.* at 389-90.

¹⁶⁹ *Id.* at 388-90. In fact, after consideration of the medical evidence offered at the hearing, the court concluded "that scientifically this type of procedure is a 'perfect' transplant." *Id.* at 389.

¹⁷⁰ *Id.* at 391.

¹⁷¹ *ANNAS ET AL.*, *supra* note 69, at 87-89 (discussing proxy consent as contradiction in terms).

¹⁷² See Goldstein, *supra* note 90, at 702 (noting that we are not "unambiguously committed to human dignity").

¹⁷³ See CALABRESI & BOBBIT, *supra* note 26, at 195-99; see also Calabresi, *supra* note 27, at 393 (advocating experimental control system that balances present against future lives and preserves choice).

¹⁷⁴ Katz, *Informed Consent*, *supra* note 89, at 174.

The resulting tensions have had a significant impact on the law of informed consent which only has made a bow toward a commitment to patients' self-determination, perhaps in an attempt to resolve these tensions by a belief that it is "less important that this commitment be total than that we believe it to be there."

Id. (citations omitted).

D. How the Standard Model Undermines Human Dignity

Although informed consent works for noncontroversial, routine experiments that are easily justified and for which consent serves only as a trivial, albeit necessary, condition, it fails us in the hard cases. If we need to perform the experiment in a difficult case, we will. If necessary, we proceed without consent or with only a perfunctory acquiescence, which may reflect desperation, resignation, or simply confusion, but certainly not a robust commitment to human dignity and autonomy. We, in fact, insult human dignity but cloak our affront beneath a fiction or formality which creates the illusion that we really do value consent, dignity, and autonomy.¹⁷⁵ In addition, when we suspect that an experiment is unethical, or simply too dangerous, we ground our objections in either "shaggy dog stories"¹⁷⁶ about how consent was not given—assuming that if it had been given, our objections would be deflected—or on an argument that the consent given was inadequate.

By focusing on the subject's state of mind instead of the conduct of the scientist, the Standard Model constrains the subject's autonomy, the very autonomy it purports to protect.¹⁷⁷ The Standard Model asks others to judge the quality of a person's subjective processes,¹⁷⁸ to decide whether they measure up to those of the mythical rational actor who, coincidentally, probably thinks and acts much like the observer. But by deconstructing and disempowering the consent, we subjugate the subject.¹⁷⁹ After all, "[i]ndividual freedom ... is guaranteed only if people are

¹⁷⁵ *Id.* at 172-74 (insisting that informed consent doctrine does not really reflect commitment to self-determination).

¹⁷⁶ See Burt, *supra* note 47, at 27 (discussing "shaggy dog stories" implemented as means of obscuring "judicial whimsy" in informed consent cases).

¹⁷⁷ See Goldstein, *supra* note 90, at 686 ("Law should establish standards of conduct for the authorities, not the citizens."). This objection is distinct from the other obvious problem with the Standard Model, that even when given, informed consent is often a mere ritual and its pretensions of serving human dignity often a fairy tale.

¹⁷⁸ See Anthony T. Kronman, *Paternalism and the Law of Contracts*, 92 YALE L.J. 763, 786 (1983) (paternalistic "cooling-off" restrictions on contractual freedom aim to cure supposed defects in agents' reasoning processes).

¹⁷⁹ See Richard J. Bonnie, *The Dignity of the Condemned*, 74 U. VA. L. REV. 1363, 1375 n.31 (1988) ("The view that the decisions of death penalty defendants or death-row inmates are never competent or voluntary undermines respect for the prisoner's autonomy while pretending to honor it."); Kronman, *supra* note 178, at 795 (asserting that paternalistic mandatory "cooling off" period "implies a moral deficiency in those to whom it applies"); Sunstein, *supra* note 6, at 1170 (warning of danger to autonomy by viewing desires and preferences as mere social constructs).

given the right to make choices which would generally be regarded as foolish."¹⁸⁰

Now, a true ethics of autonomy would require experimenters to "inform for decision," or to refrain from informing if the subject so requests. Whether the subject actually consented—in some metaphysically pure sense—would be as irrelevant as it is inscrutable.¹⁸¹ With this view, respect for human dignity does not require that we insure "informed"—read, "correct in the eyes of outsiders"—consent, but rather that self-determination be given free rein. Rules that focus on the subject's reasoning process rather than on the conduct of experimenters disserve their supposed purpose. On the other hand, informing *for* the decision, rather than judging the informedness of that decision, *does* respect human autonomy. The Standard Model of informed consent claims, but fails, to do the same. It professes "fairy tale-like optimism about human capacities for 'intelligent' choice," but demonstrates a "mythic pessimism of human capacities to be choice-makers."¹⁸²

But are we content with the ethics of autonomy? Our dignity may be analytically and morally prior to our autonomy. Dignity may require respecting autonomy-as-free-choice in some circumstances, but at the same time it may also require objective limits on practices, behaviors, procedures, and institutions which are in themselves inconsistent with the dignity of persons. We have designated respect for consent as a marker for or indication of respect for human dignity, hence consent's justificatory force in our culture, but what if that designation is mistaken?

The "informing for decision" model does not imply limits on what may be consented to.¹⁸³ To mark off certain practices and experiments as *per se* prohibited requires going beyond informing for decision, beyond merely guaranteeing an information-rich

¹⁸⁰ Annas, *The Hospital*, *supra* note 131, at 13. See also *In re President & Dirs. of Georgetown College, Inc.*, 331 F.2d 1010, 1016-17 (D.C.Cir. 1964) (Burger, J., dissenting from denial of rehearing) (interpreting Brandeis' famous "right to be let alone" as including "a great many foolish, unreasonable and even absurd ideas which do not conform, such as refusing medical treatment even at great risk").

¹⁸¹ Goldstein, *supra* note 90, at 693-94. See also George J. Annas, *Breast Cancer: The Treatment of Choice*, in *JUDGING MEDICINE*, *supra* note 55, at 36, 38 (arguing that self determination does not require that patients be informed; they may opt out of receiving information).

¹⁸² Katz, *Informed Consent*, *supra* note 89, at 174.

¹⁸³ See Goldstein, *supra* note 90, at 695-96 (noting that although there may indeed be such limits, state may not impose their observance).

space for choice, free from second-guessing. However, our ethic of public life and personal relations is constructed around a belief in the justifying force of consent. We are reluctant to limit consensual activity, not only because we—positively—respect consent, but because we—negatively—do not know what other notions to turn to. If we trim consent's power, even with the purpose of guarding human dignity, what do we have left?

The next part of this Article discusses human experimentation in a way which allows us to prohibit or condemn immoral experiments or experimenters, without deconstructing the subjects' rationality and autonomy. Consent might still be the unalterable ground rule—the necessary condition for a moral experiment—but it is a rule supplemented by others, as was the case with the Nuremberg Code. And one of these rules might be that some experiments may not be consented to, not because something is wrong with the subject, but because something is wrong with the experiment.¹⁸⁴

V. ALTERNATIVES TO THE ETHICS OF AUTONOMY

We have previously established that the Standard Model of informed consent is at best a subterfuge; it fails both to protect research subjects from harmful experiments—assuming they need protection—and to promote the dignity of the human person.¹⁸⁵ Most research poses no problems and is easily legitimated and justified, but the subject's consent to those experiments is not by itself a reliable indicator that they are justified, nor is it itself what justifies them.

It is clear that we sometimes limit consensual activity. Although some of these limits are controversial,¹⁸⁶ many are not. Why and when do we interfere? It is a complicated problem. Limits on the power to consent may sometimes reflect our judgment about a particular activity or choice, but they may also

¹⁸⁴ In a very different context, Professor Stephen Schwarcz, discussing the taking and granting of security interests in body parts, put the issue very nicely: "[T]he threshold question is whether such security interests *should* be permitted. That issue transcends commercial law. Only when that issue is resolved can one begin to address *how* to create and perfect the security interest" Stephen L. Schwarcz, *A Fundamental Inquiry into the Statutory Rulemaking Process of Private Legislatures*, 29 GA. L. REV. 909, 945 (1995) (emphasis added).

¹⁸⁵ See *supra* notes 109-184 and accompanying text.

¹⁸⁶ See, e.g., *Bowers v. Hardwick*, 478 U.S. 186 (1986) (upholding state law prohibiting consensual sexual activity).

speak to the relationships and contexts in which these activities and choices occur.¹⁸⁷ And the reasons given for interfering with consent, with autonomy, matter a great deal. Think back to the critique of the Standard Model of informed consent: By refusing to allow an experiment—by interfering with a private preference—we either degrade the would-be subject by questioning the quality of his consent,¹⁸⁸ or respect him, by accepting his consent at face value. But we can also respect the subject—and ourselves—by forbidding the experiment outright; whether our prohibition reflects respect or not depends on why we interfere with his choice. The immediate and strident objection, however, is that idealistic harangues about the insufficiency of consent as a justification for experiments are odiously paternalistic. Therefore, before discussing the possibility of dignity-protecting restrictions on consent to human experimentation, we should ventilate this paternalism objection.

A. *Beyond Paternalism*

A restriction on the power of consent is paternalistic “if the sole justification for imposing it is to promote or protect the individual’s own welfare (or happiness or good).”¹⁸⁹ Given our culture’s dedication to the force of consent, our “master concept,” and to autonomy, the paternalism objection is a forceful one. If a limit on consent, say, to human experimentation, is “paternalistic” and is therefore inimical to the dignity of persons, then the ostensible reason for the limit, to protect dignity, collapses and the limit is unjustified.¹⁹⁰

¹⁸⁷ See Sunstein, *supra* note 6, at 1138-39 (providing various reasons for interferences with private preferences); see also Cass Sunstein, *Disrupting Voluntary Transactions*, in *MARKETS AND JUSTICE*, NOMOS XXXI, 279 (John W. Chapman & J. Ronald Pennock, eds., 1989).

¹⁸⁸ See Isaiah Berlin, *FOUR ESSAYS ON LIBERTY* 137 (1969) (suggesting that to interfere with autonomous choice of individuals is to “deny their human essence, to treat them as objects without wills of their own, and therefore to degrade them”).

¹⁸⁹ See ANTHONY KRONMAN & RICHARD POSNER, *THE ECONOMICS OF CONTRACT LAW* 254 (1979); see also Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 *HARV. L. REV.* 1089, 1113-14 (1972) (distinguishing paternalism from rules based on “God’s interest” because paternalism implies “looking after the interests of the other party.”); Sunstein, *supra* note 6, at 1171 (noting that “the troublesome nature of [paternalism] ... stems from the fact that the government is claiming to know better than the individual whether a particular course of action will serve that individual’s interests”); see generally *PATERNALISM* (Rolf Sartorius ed. 1983).

¹⁹⁰ It is not clear, however, that all forms of paternalism are inconsistent with re-

John Stuart Mill railed against paternalism,¹⁹¹ and we have since followed his lead. The case against paternalism was eloquently stated by Justice Brandeis:

Experience should teach us to be most on our guard to protect liberty when the Government's purposes are beneficent. Men born to freedom are naturally alert to repel invasion of their liberty by evil-minded rulers. The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding.¹⁹²

Brandeis' warning strikes a nerve in our cultural consciousness; notwithstanding its ubiquity in our institutions,¹⁹³ we are hostile to paternalism.¹⁹⁴

This hostility to paternalism is evident in the controversy over human experimentation. For example, in the debate over experimental AIDS treatment and research,¹⁹⁵ activists and patients insist, "Give us the drugs! Do the research! We'll take the risks!" In their view, "the subject is respected best not by protection against research risks but by ensuring freedom of choice and participation in research."¹⁹⁶ The plight of persons with AIDS demands that we explain and justify why we insist on protecting those who would, if permitted, refuse our protection.¹⁹⁷

spect for persons. As Professor Kronman has discussed, we are really faced with several forms of paternalism, each motivated by different concerns. See generally Kronman, *supra* note 178, at 765. In this essay, I criticize the paternalism that substitutes the judgment of one for the judgment of another on the ground that the one perceives the other's own interest differently, and would not have made the other's choice had he been in the other's position. This form of paternalism is the type I see lurking beneath the standard model of informed consent.

¹⁹¹ Mill insisted that "the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant." MILL, *supra* note 18, at 68.

¹⁹² *Olmstead v. United States*, 277 U.S. 438, 479 (1928) (Brandeis, J., dissenting).

¹⁹³ See Kronman, *supra* note 178, at 795 ("Our legal system restricts contractual freedom in many ways and for many reasons."); Sunstein, *supra* note 6 at 1173 ("[S]ignificant dangers lie in any approach that would treat private preferences, as expressed in markets, as exogenous variables"). But see, Duncan Kennedy, *Distributive and Paternalist Motives in Contract and Tort Law, with Special Reference to Compulsory Terms and Unequal Bargaining Power*, 41 MD. L. REV. 563, 624-49 (1982) (defending paternalism against claim that it is inconsistent with legal order).

¹⁹⁴ On our deep distrust of paternalism, see generally David L. Shapiro, *Courts, Legislatures, and Paternalism*, 74 U. VA. L. REV. 519 (1988).

¹⁹⁵ See *supra* note 44.

¹⁹⁶ Mariner, *supra* note 44, at 291.

¹⁹⁷ Recall the discussion of limits on prisoners' ability to participate in research, despite their own wish to do so and their quite rational expectations of personal

These persons also rightly demand more by way of justification than our patronizing insistence that they have mistakenly calculated their own interests and that we know what is best for them.

How do we move the debate beyond paternalism? What does a commitment to human dignity and respect for persons require? The Standard Model is no help here; it is itself incurably paternalistic, when it rises above being a ritualistic fairy tale.¹⁹⁸ The Standard Model assumes it can shepherd misguided subjects to their truer, more autonomous selves.¹⁹⁹ But many limits on private preferences do not require us to unpack consent or re-evaluate others' choices. There are non-paternalistic motivations and reasons for limiting opportunities to consent, or for curtailing consent's justification force.

For example, in the context of AIDS research, as in any human experimentation context, "the first and most important question is whether the experiment should be done at all."²⁰⁰ Only after this question is answered should we ask about consent. The framework for AIDS research and other experimentation must be defined in objective and not subjective terms. As one commentator put it, "[t]he applicability of ethical principles should not depend on the participants' willingness to have them apply in any particular case ... [t]his cannot depend on the subject's willingness to take particular risks any more than a person's agreement to be a slave justifies slavery."²⁰¹ Thus, in *Kaimowitz*, the issue should not have been whether the decision to undergo the surgery was or was not "rational."²⁰² It may have

benefits. See generally *supra* notes 107-30 and accompanying text.

¹⁹⁸ See e.g., Katz, *Informed Consent*, *supra* note 89, at 140 ("Medical law in the United States is a clear case of institutionalized paternalism.").

¹⁹⁹ See Sunstein, *supra* note 6, at 1141-42 (arguing that interferences with private preferences are justified when aimed at producing more autonomous choice, free from influence of ignorance, bad habits, or patriarchal rules).

²⁰⁰ See Annas, *Faith*, *supra* note 44, at 778; see also *United States v. Rutherford*, 442 U.S. 544 (1979) (denying exception to FDA rules for terminally ill cancer patients seeking Laetrile for treatment).

²⁰¹ Mariner, *supra* note 44, at 295 ("Society always labels some risks . . . unacceptable").

²⁰² After a lengthy analysis of the three elements of informed consent: (1) Disclosure to patient of information necessary to make an intelligent decision; (2) Patient's knowledge of the risk involved; and (3) A voluntary choice by the patient, the court held that an involuntary detained mental patient can not give an informed and valid consent to *experimental* psychosurgery. *Kaimowitz v. Dep't of Mental Health for the State of Mich.*, reprinted in 1 MENTAL DISABILITY L. REP. 147, 150-51, 153 (1976) (emphasis added). However the court added that a mental patient

been. However, other factors—Doe's status as a prisoner, the novelty of the technique, the sacredness of the brain, human dignity—dictate that his consent may not serve as blanket authorization to proceed in good conscience.²⁰³ We should limit Doe's ability to consent, or more precisely, Doe should not even be asked for his consent, to protect ourselves from participating in a bad act. Because psychosurgery is intrinsically incompatible with a respect for human persons, the focus is not to insure that Doe acts within what we perceive to be his best interest. We should worry about the behavior of the experimenter, about our own culpability, and not about the subject's choosing capacities.

Such restrictions on consent, which aim at objective behaviors and results rather than at subjective decision-making processes, are common in the criminal law. For example, guilty pleas must usually be supported by a factual basis, and be knowing and voluntary.²⁰⁴ We recognize that defendants might quite rationally plead guilty to crimes they did not commit and that prosecutors might be willing to accept such pleas.²⁰⁵ However, because such pleas embroil the legal system in a monstrous falsehood, we refuse to accept them while admitting that they might indeed be in the defendant's correctly perceived best interests.

In *Newton v. Rumery*,²⁰⁶ the Supreme Court reversed a lower court's decision that a "release-dismissal agreement," by which Rumery agreed to release any claims he might have against the Town in exchange for the prosecutor dropping pending charges against him, was unenforceable as a violation of public policy.²⁰⁷ The Court noted that in many cases, such agreements reflect a reasoned and rational decision that the very tangible benefits of

could give informed consent to an *accepted* psychosurgical procedure. *Id.* at 153 (emphasis added).

²⁰³ Burt, *supra* note 47, at 34.

²⁰⁴ See, e.g., Fed. R. Crim. P. 11(f) (requiring inquiry into factual basis of plea); see also John L. Barkai, *Accuracy Inquiries for All Felony and Misdemeanor Pleas: Voluntary Pleas But Innocent Defendants?*, 126 U. PA. L. REV. 88, 89 n.6 (1977) (listing numerous state statutes with some form of factual basis requirement); see generally Bonnie, *supra* note 184, at 1369-80 (discussing how factual basis requirement serves interests of both society and defendant).

²⁰⁵ See *North Carolina v. Alford*, 400 U.S. 25 (1970) (approving plea despite defendant's insistence that he was innocent "in view of the strong factual basis for the plea"); see generally Barkai, *supra* note 204, at 96-7 (discussing possible reasons factually innocent defendants might decide to plead guilty).

²⁰⁶ 480 U.S. 386 (1987).

²⁰⁷ *Id.* at 392-97.

avoiding prosecution outweigh the more speculative hopes of a civil judgment.²⁰⁸ In dissent, Justice Stevens insisted that,

[the examination of the agreement] cannot end with the observation that respondent made a knowing and voluntary choice to sign a settlement agreement. *Even an intelligent and informed, but completely innocent, person accused of crime should not be required to choose between a threatened indictment and trial ... and surrendering the right to a civil remedy*²⁰⁹

This is because "the important federal interests in providing a remedy for the violation of constitutional rights and in having the merits of such claims resolved openly" outweigh the interests in enforcing such agreements.²¹⁰

²⁰⁸ *Id.* at 394.

²⁰⁹ *Id.* at 403 (Stevens, J., dissenting) (emphasis added).

²¹⁰ *Id.* at 418-19 (Stevens, J., dissenting). Contrast Justice Stevens' approach with the Court's "next friend" jurisprudence in "volunteer" death penalty cases. The Court has generally assumed that the only question is whether the defendant is competent to make his own decision. In fact, capital defendants often refuse to fight their executions. See, e.g., Abraham Kwok & Pamela Manson, *Brewer is Executed, 1st Lethal Injection Given in Arizona*, ARIZONA REPUB., March 3, 1993, at A1 (quoting condemned prisoner, "I just don't think I deserve to live. I killed."); see generally Jane L. McClellan, Comment, *Stopping the Rush to the Death House: Third Party Standing in Death Row Volunteer Cases*, 26 ARIZ. ST. L.J. 201, 213-16 (1994) (discussing death penalty volunteers' motives to waive appeals); Welsh S. White, *Defendants Who Elect Execution*, 48 U. PITT. L. REV. 853, 871-75 (1987) (discussing psychological factors and motives which influence inmates to choose death). For the most part, courts accept these decisions, barring some demonstration of the defendant's near-insanity. See, e.g., *Brewer v. Lewis*, 997 F.2d 550, 561-63 (9th Cir. 1993) (Reinhardt, J., dissenting from failure to grant en banc review); *Demosthenes v. Baal*, 495 U.S. 731, 734-36 (1990) (holding defendant was competent to waive review); *Gilmore v. Utah*, 429 U.S. 1012, 1017 (1976) (Stevens, J., concurring) ("next friend" doctrine does not apply where defendant has knowingly waived right to proceed). The problem is that the defendant's choice to accept execution may cause tangible harm to third parties, or may result in a death sentence, which has not been properly adjudicated, being carried out despite legal or constitutional flaws. For example, in both *Whitmore* and *Gilmore*, the death sentences were never appealed.

Gary Gilmore's case is the most famous and perhaps poignant example of the harm caused by voluntary execution. Gilmore's sentence may have been unconstitutional, but was never appealed. Gary Gilmore's mother Bessie Gilmore attempted and failed to challenge Gilmore's death sentence. *Gilmore*, 429 U.S. 1012. The Court focused on her technical standing to present her claims, arguably ignoring the real and unfolding human drama. *Id.* at 1014-16. "They also left a red handknit shawl with her, and fluffy house slippers to keep her feet warm. Somehow, they had never got around to talking of Bessie's case in the Supreme Court." MAILER, *supra* note 8, at 732.

For fuller treatment of the issues that arise when a defendant—and a client—chooses death, see Bonnie, *supra* note 179, at 1391 (1988) (insisting that "the law's duty to respect individual dignity is heightened, not diminished, when choices

Similarly, in contract and consumer law, we often balance our general preference for unfettered respect for consensual arrangements against other concerns.²¹¹ Some of these concerns may be paternalistic, aimed at protecting one of the parties from disregarding his or her own interests; but they may also aim at increasing systemic efficiency or societal respect for human dignity.²¹² Of course, the aims of any given limit on a person's ability to consent to an act, or to contract, are probably mixed. A nonwaivable warrant of habitability, the prohibitions of contracts of slavery or peonage, of agreements purporting to waive the right to obtain a divorce, of many provisions requiring specific performance, the voidability of contracts made by infants, and the nonwaivable "cooling off" period imposed by consumer law in many transactions—all of these apparent anomalies in our generally consent-driven law are motivated both by paternalistic and other concerns.²¹³ One purpose of these rules is undeniably to substitute the supposedly better judgment of the legislature and the judiciary about what is really in a person's best interest.²¹⁴ Therefore, to the extent that we disapprove of paternalism, we may dislike these rules. But another purpose of these rules is to protect third parties or to vindicate larger social goals, without inquiring at all into the "real" interests or capacities of the regulated parties.²¹⁵

Whether a given limit is paternalistic or something else may be only a question of perspective. Maybe we require a non-

are made in the shadow of death"); White, *supra* at 855-61 (noting dilemma faced by defense attorneys when client decides to accept execution).

²¹¹ For example, under § 2-302 of the Uniform Commercial Code, a court may declare a contract "unconscionable" and thus refuse to enforce its terms. Likewise, in an attempt to protect the consumer, many provisions of the sales law alter the exact nature of the transaction: warranties are implied (§ 2-314, § 2-315), and a merchant's ability to exclude the implied warranties is limited (§ 2-316, § 2-317). SELECTED COMMERCIAL STATUTES (West 1994).

²¹² See generally KRONMAN & POSNER, *supra* note 189, at 253-61; Kronman, *supra* note 183.

²¹³ See Kronman, *supra* note 178, at 764 (stating that some limitations seek to protect moral and economic interests as well).

²¹⁴ See, e.g., James G. Dwyer, *Parents' Religion and Children's Welfare: Debunking the Doctrine of Parents' Rights*, 82 CAL. L. REV. 1371, 1431 (1994) (stating that legislatures might use substituted-judgment framework to decide which child-rearing decisions should reside with state and to settle disputes involving proposed medical care for mentally retarded adults).

²¹⁵ See Kronman, *supra* note 178, at 765 (stating that some paternalistic limitations on contractual freedom can be explained by considerations of economic efficiency and distributive fairness).

waivable warrant of habitability because we think that some people might foolishly agree to bad housing to save a few dollars, or perhaps we, as a community, do not want our goal of decent housing stock to be stymied by purely self-interested transactions.²¹⁶ We interfere even as we remain agnostic about whether a waiver would be in those people's self-interest.

The Nuremberg Code explicitly recognized the need to place non-paternalistic limits on the scope of experiments.²¹⁷ The Code asks more of an experiment, a researcher, or society than mere consent.²¹⁸ There are nine other principles, at least some of which must be considered before consent is even solicited.²¹⁹ Whether someone consents to an experiment which fails to meet the criteria set forth in the rest of the Code is irrelevant; if he does not consent, then any experiment is undeniably wrong. However, if he does consent to the experiment, this consent alone will not justify it.²²⁰ Importantly, though, it is not the ability or "right" of the subject to consent which is questioned by such an approach. What is being questioned are the situations when questions of consent are relevant.

Preferences may be, and often are, limited for non-paternalistic reasons. Paternalism may conflict with human dignity, but so does the Standard Model of informed consent. Thus, the following sections approach the questions of how and whether to limit the efficacy of consent to human experimentation from three different but related points of view. All three approaches are non-paternalistic and embody a richer notion of human dignity and of human flourishing than those notions implicit in the Standard Model of informed consent.

B. A Triadic Approach

The Standard Model works through the "socially sanctioned

²¹⁶ *Id.* at 764 (noting that such provisions in a residential lease may have paternalistic or non-paternalistic purpose).

²¹⁷ See generally Annas, *Mengele's Birthmark*, *supra* note 45, at 20 n.12 (listing Nuremberg Code's legal requirements for experimentation on humans).

²¹⁸ See, e.g., *id.* (listing requirements of Code that experiments be conducted only by scientifically qualified persons and that adequate facilities are provided and proper preparations made for experiments).

²¹⁹ *Id.* at 21.

²²⁰ See *id.* at 20-21; Edmond Cahn, *Drug Experiments and the Public Conscience*, in EXPERIMENTATION, *supra* note 50, at 721 (discussing factors, other than subject's capacity to choose, which might render consent to experiment morally ineffective).

dyad" of experimenter and subject.²²¹ The former seeks the consent of the latter; the whole affair looks nicely contractual and free. Conveniently, the arrangement is the kind that our legal system understands—the usual litigation paradigm, a conflict between two disputants advancing opposing interests.²²² But this picture is not appropriate in experimentation cases; these cases are instead "triadic."²²³ There is a third interest—*our* interest—in preserving human dignity in our community. In the Standard Model, this third interest—the "silent, but influential and omnipresent participant"²²⁴—is ignored. However, we non-subjects are interested parties, and we either "suffer or benefit from experiments or from the failure to perform [them]."²²⁵

How can we, as bystanders, take our place at the table, and convert the dyad into a triad? Think of limits on the justifying power of consent as a proxy for our involvement in the experimentation decision. We cannot always be there to insure that degrading, consensual experiments do not occur, so we preemptively voice our opposition through limits. These limits on consent are not imposed as ad hoc and particularistic reactions to the troubling facts in a particular case, as when consent is given by a person with diminished capacities. Instead, they represent a systematic intervention and reflect a system-wide concern that we, as interested parties, are being excluded from the table where decisions that affect our community and its values are being made.

Strictly speaking, of course, we do not insert ourselves into the conversation between researcher and subject so much as we preclude certain conversations from taking place. Under the "triadic" approach, we do not allow subjects' consent to be solicited for degrading experiments, not because we worry that the subjects are incapable of consenting rationally, but because we have decided that the experiments should not occur, that certain

²²¹ Burt, *supra* note 47, at 26.

²²² *Id.* at 29 (criticizing court's approach in *Kaimowitz*).

²²³ *Id.* at 25, 29-34. In Burt's paper, he identifies the three points of the "triad" as researcher, subject, and reviewing court, and questions whether this triad is up to the task of regulating psychosurgery. *Id.* at 25. I have replaced the third point—the court—with *all of us*, who have an interest in insuring that our community is one in which dignity is respected. See Pope Pius XII, *supra* note 59, at 91 (listing and weighing interests of science, patient, and community in medical research).

²²⁴ Burt, *supra* note 47, at 29.

²²⁵ See Walter Modell, *The Ethical Obligations to the Nonsubject*, in *EXPERIMENTATION*, *supra* note 50, at 723.

relationships ought not to be created. Through our surrogate intrusion into the experimental dyad, we bridge the wide divide of social, emotional, and moral distance between ourselves and the two nominal parties to the transaction,²²⁶ and we protect ourselves from complicity in the degradation of human persons.²²⁷

C. A Constitutional Approach: "Self-Paternalism"

This related but distinct perspective begins from the idea of "self-paternalism."²²⁸ We behave self-paternalistically when we limit ourselves in the short run to vindicate another, long-term commitment.²²⁹ The classic example is Odysseus lashing himself to the mast of his ship so that the Sirens' song would not entice him to their island. When generalized from the individual's standpoint to that of a society, self-paternalism is really "constitutionalism."²³⁰ Laws often reflect a society's "preferences

²²⁶ Burt, *supra* note 47, at 34. Some might suggest that the IRBs effectively perform the function of surrogate for our interests in the triad. But given the institutional ties between the IRBs and researchers, and the IRBs' place in the dignity-defeating Standard Model of informed consent, they are simply not up to the job.

²²⁷ The goal of protecting ourselves as a community from complicity in degradation should be distinguished from a goal of promoting the "rights of the community" to, for example, protect people from themselves, or save itself from paying the financial costs of experiments gone awry. In *Tennessee v. Pack*, 527 S.W.2d 99, 113 (Tenn. 1975), *cert. denied*, 424 U.S. 954 (1976), the court acknowledged the pull of religious freedom, but held that "snake-handling" as part of a religious ritual was a nuisance. It stated:

Tennessee has the right to guard against the unnecessary creation of widows and orphans. Our state and nation have an interest in having a strong, healthy, robust, taxpaying citizenry capable of self-support and of bearing arms and adding to the resources and reserves of manpower. We, therefore, have a substantial and compelling state interest [in prohibiting snake-handling]....

Id. What I am suggesting in this essay is not that we need to throw more "rights" into the mix, but that we should not let the ethics of autonomy and consent thwart our commitments to relationships predicated on respect for human dignity.

²²⁸ See generally GUIDO CALABRESI, *IDEALS, BELIEFS, ATTITUDES, AND THE LAW* 12 (1985) (explaining that self-paternalism is forcing yourself to do what is best for yourself); JON ELSTER, *ULYSSES AND THE SIRENS* (rev. ed. 1984); Calabresi & Melamed, *supra* note 189, at 1113-15 (distinguishing between self-paternalism and true paternalism); Sunstein, *supra* note 6, at 1140-45 (discussing voluntary foreclosure of consumption choices by majority); Bailey Kuklin, *Self-Paternalism in the Marketplace*, 60 U. CIN. L. REV. 649 (1992) (explaining consumer's use of self-paternalism as device to protect herself from unavoidable disadvantage in marketplace); Jonathan Schonsheck, *Deconstructing Community Self-Paternalism*, 10 LAW & PHIL. 29 (1991).

²²⁹ CALABRESI, *supra* note 228, at 12.

²³⁰ When the theory of self-paternalism is extended to society, one has to posit a

about preferences,²³¹ and its decision to voluntarily foreclose future choices. Our Constitution is an example.²³² Because the framers knew the dangers of policy based on emergency and expediency, and the occasional attractiveness of utility-based or even bigotry-based action, it made sense to prospectively limit what government could do to us and what we could do to each other and ourselves.²³³ In a way, our constitutional rights reflect our "second-order preferences"²³⁴ about the conduct of future majorities.²³⁵

Importantly, "constitutionalism" is neither convenient nor cost-free. Requiring the government to pay "just compensation" when it takes and uses our property,²³⁶ that punishments be humane and proportional,²³⁷ and that police and prosecutor restrain their zeal in the face of an endless parade of obviously guilty defendants and public outcry about crime is very inconvenient.²³⁸ But we have lashed ourselves to a constitutional ideal, fearing how we might react in future perceived emergencies. In so doing, we have "recognize[d] [our] inherent weaknesses and [sought] to compensate for them by means of a Constitution ... our insulation from our baser selves."²³⁹

The Eighth Amendment's prohibition of excessive and disproportional punishment embodies this strong sense of constitutional self-paternalism. Through this amendment, "We The

unanimous citizenry agreeing to bind themselves from future mistakes. If only the majority wishes to bind itself, the minority are coerced. See Schonsheck, *supra* note 228, at 35, 48; Sunstein, *supra* note 6, at 1141-42.

²³¹ Sunstein, *supra* note 6, at 1140.

²³² KRONMAN & POSNER, *supra* note 189, at 258-59 (anti-slavery rules may be justified because they offend Constitutional values).

²³³ See *New York v. United States*, 112 S. Ct. 2408, 2434 (1992) ("[T]he Constitution protects us from our own best intentions: It divides power among sovereigns and among branches of government precisely so that we may resist the temptation to concentrate power in one location as an expedient solution to the crisis of the day."); Sunstein, *supra* note 6, at 1141 ("The majority is seeking to bind itself, and the legal system is the best way to accomplish that task.").

²³⁴ Sunstein, *supra* note 6, at 1140. Second order preferences are "preferences about preferences," or conscious choices of preferences, by the majority because it disapproves of some conduct. *Id.* at 1140-41.

²³⁵ See *id.* at 1141; LAURENCE H. TRIBE, *AMERICAN CONSTITUTIONAL LAW* § 11-1 (1978).

²³⁶ U.S. CONST. amend. V.

²³⁷ U.S. CONST. amend. VIII.

²³⁸ U.S. CONST. amend. IV.

²³⁹ *Furman v. Georgia*, 408 U.S. 238, 345 (1972) (Marshall, J., concurring) (discussing Eighth Amendment's limitations).

People" have expressed our commitment to a society free from human degradation:²⁴⁰ "[O]ur Constitution is not grounded in sympathy for those who would commit crimes of violence, but in concern for the society that diminishes itself whenever it takes the life of one of its members."²⁴¹ Under the Eighth Amendment, it is not just that the criminal defendant has a claim or right against society, but that we have bound ourselves against doing certain things to defendants.²⁴² The Eighth Amendment clearly reflects its drafters' foresight and desire to restrain both themselves and those who followed.²⁴³ Because the amendment is a self-directed command, and not just a defendant's personal right,²⁴⁴ the defendant may not waive it.²⁴⁵ No defendant could ever meaningfully consent to an Eighth Amendment violation; after all, who is he to demand that we violate our moral commitments?²⁴⁶ We cannot accept such consent.²⁴⁷

²⁴⁰ See *Furman*, 408 U.S. at 297 (Brennan, J., concurring) ("Today we reject public executions as debasing and brutalizing to us all.").

²⁴¹ *People v. Anderson*, 493 P.2d 880, 899 (Cal. 1972), *cert. denied*, 406 U.S. 958 (1972).

²⁴² See Stephen A. Blum, *Public Executions: Understanding the "Cruel and Unusual Punishments" Clause*, 19 HASTINGS CONST. L.Q. 413, 449-50 (1992) (discussing that Eighth Amendment should not be viewed as personalized protection for prisoner).

²⁴³ See *id.* at 438-54; *Weems v. United States*, 217 U.S. 349, 373 (1910) (noting that Framers believed "power might be tempted to cruelty"); *Furman*, 408 U.S. at 320 (Marshall, J., concurring) (quoting Patrick Henry's warnings that "no latitude ought to be left nor dependence put on the virtue of representatives" since they may use some pretense to introduce harsher punishments).

²⁴⁴ See Blum, *supra* note 242, at 449 ("Eighth Amendment decisions revolve not around the punished but around the punisher.").

²⁴⁵ See Linda E. Carter, *Maintaining Systemic Integrity in Capital Cases: The Use of Court-Appointed Counsel to Present Mitigating Evidence When the Defendant Advocates Death*, 55 TENN. L. REV. 95, 128 (1987) ("Limits on an individual defendant's ability to waive constitutional rights are warranted when society's interests are balanced against those of the defendant.").

²⁴⁶ Justice Holmes commented, "Just as the original punishment would be imposed without regard to the prisoner's consent and in the teeth of his will, whether he liked it or not, the public welfare, not his consent, determines what shall be done." *Biddle v. Perovich*, 274 U.S. 480, 486 (1927). See also *Commonwealth v. McKenna*, 383 A.2d 174, 180-81 (Pa. 1978) (given societal interests, defendant cannot waive rights to determination that his death sentence is constitutional). But see *Bonnie*, *supra* note 179, at 1384-91 (suggesting that societal interests underlying Eighth Amendment might not outweigh defendant's right to consent to his execution).

²⁴⁷ "The moral impossibility is on the other side, *our* side. It is we who *cannot accept* certain consents that are ostensibly free and voluntary; it is we who are unable to accept a profit from human sacrifice." Cahn, *supra* note 220, at 721; see also West, *supra* note 7, at 399 (noting that consensual-but-degrading relations are dam-

Categorical limitations on human research and experimentation, like limits on police power, unavoidably slow us down and may have unfortunate and bitterly resented results.²⁴⁸ For example, we might never learn a great deal about children's diseases and health. Many might die of AIDS who would otherwise be willing to take risks on the slight chance that the next miracle drug might really work. We also might not certainly know that a certain gas mask will protect our soldiers overseas. But these losses might be—like the occasional guilty defendant going free—a price worth paying. The question is not so much whether we can afford to honor our commitment to human dignity, free from subterfuges like the Standard Model of informed consent, but whether we can afford not to, or whether we ought to.²⁴⁹

Thus, we limit consent's effect in human experimentation because, like Odysseus, we doubt our ability to stand firm in the face of the Sirens' song. The lure of perfectionism and of the all-consuming pursuit of knowledge, both the conceit and the curiosity of the scientist, all conspire to tempt us to play fast and loose with the dignity of our research subjects and ourselves. To prevent ourselves from self-betrayal, we lash ourselves to the ideal of respect for persons, concretely embodied in objective and non-waiveable side-constraints in human experimentation.²⁵⁰ The ideals by which we limit our research are "the product of our own moral self-image, our enduring convictions and our social conscience."²⁵¹

D. The Inalienability of Our Dignity

The third approach is essentialist or teleological. Because of what it means to be a person, because of our ideal of human flourishing, and because we recognize certain acts, which degrade human dignity, as inherently inimical to our ideal, we

aging to autonomy and that "[i]t is immoral to participate in such consensual transactions and immoral for the community to tolerate them.").

²⁴⁸ "I must acknowledge that research in psychosurgery will most likely be slowed, perhaps by decades, by barring access to these experimental subjects. That is an important social cost of my conclusion." Burt, *supra* note 47, at 34.

²⁴⁹ See Jonas, *supra* note 22, at 228 ("Society ... cannot 'afford' a single miscarriage of justice, a single inequity in the dispensation of its laws, the violation of the rights of even the tiniest minority, because these undermine the moral basis on which society's existence rests.").

²⁵⁰ See Burt, *supra* note 47, at 34.

²⁵¹ Cahn, *supra* note 220, at 721.

prohibit them directly.²⁵² Because it would simply be wrong to do certain things, consenting to having those things done to oneself does not, and cannot, justify them.²⁵³ We lack the power to justify anti-human acts by our consent.

Pope Pius XII once told researchers that:

[T]he Patient cannot confer rights he does not possess ... the decisive point is the moral licitness of the right a patient has to dispose of himself. Here is the moral limit to the doctors' action[s].²⁵⁴

That is, the dignity of one's personhood is inalienable. The recent Catechism of the Catholic Church expands on this idea.²⁵⁵ Although the value and usefulness of science is acknowledged and embraced,²⁵⁶ this utility does not and cannot provide the guiding moral principles for research.²⁵⁷ Rather, the "dignity of the person" is the inviolable norm governing human experimentation:

Research or experimentation on the human being cannot legitimate acts that are in themselves contrary to the dignity of persons and to the moral law. The subjects' potential consent does not justify such acts.²⁵⁸

In a similar vein, one commentator wrote, in the midst of the abolition debates, that "[t]o say that by committing the folly or the crime of contracting to do an immoral act a man lays himself under a moral obligation to do that immoral act is to overturn

²⁵² Of course, there is the danger that the imposition of a community's ideal of human flourishing on a dissenter effectively violates the Kantian noninstrumentalization principle, and uses the dissenter as a means to the community's end. See Schonsheck, *supra* note 228, at 43 n.15.

²⁵³ See Marcia Angell, *Editorial Responsibility: Protecting Human Rights by Restricting Publication of Unethical Research*, in *THE NAZI DOCTORS*, *supra* note 44, at 278 ("[I]nformed consent cannot transform an inherently unethical experiment into an ethical one.").

²⁵⁴ See Pope Pius XII, *supra* note 59, at 92.

²⁵⁵ CATECHISM OF THE CATHOLIC CHURCH § 2292-96 (1994) [hereinafter CATECHISM] (explaining respect for persons when dealing with scientific research).

²⁵⁶ *Id.* at §§ 2292-94 ("Science and technology are precious resources when placed at the service of man and promote his integral development for the benefit of all."). See also POPE PIUS XII, *supra* note 59, at 91 (emphasizing intrinsic value of scientific knowledge).

²⁵⁷ See CATECHISM, *supra* note 255, at § 2294.

²⁵⁸ *Id.* at § 2295. This passage also notes that experimentation that takes place without the subject's informed consent is *per se* a violation of human dignity. Informed consent is a necessary but not a sufficient condition. *Id.*

the very foundations of morality."²⁵⁹ It is not that we paternalistically limit otherwise justifying consent, but rather that consent in these instances is intrinsically limited.²⁶⁰ The would-be consentor is morally powerless.

This third approach seems to capture the heart of the Nuremberg Code, its "deep theory," shrouded over by years of haggling about informed consent. After all, the focus at Nuremberg was not on the lack of consent given by the Nazis' victims, but on the horrific aspects of the acts themselves.²⁶¹ The very purpose of the trial, General Taylor said, was "as the voice of humanity, [to] stamp these acts, and the ideas which engendered them, as barbarous and criminal."²⁶² To focus on consent as the lesson of Nuremberg, and to identify consent as the primary locus for moral concern in human experimentation, misses the point. One commentator has said:

It would be a moral understatement to conclude that the Nazi experiments were wrong because voluntary, informed consent was not obtained from the subjects Two fundamental ethical principles were simultaneously violated: the prohibition against inflicting suffering on human beings and the Kantian categorical imperative prohibiting the use of persons as mere means to the ends of others.²⁶³

This third approach also sounds in the American historical tradition. After all, we ringingly proclaimed to the world the existence of certain "inalienable" rights: Life, liberty, and the

²⁵⁹ Anonymous, *Has Slavery in the United States a Legal Basis?*, 2 MASS. Q. REV. 147 (1848).

²⁶⁰ Immanuel Kant, *LECTURES ON ETHICS* 165 (L. Infield trans., J. MacMurray rev. ed. 1930).

Man cannot dispose over himself because he is not a thing; he is not his own property; to say that he is would be self-contradictory; for in so far as he is a person he is a Subject in whom the ownership of things can be vested, and if he were his own property, he would be a thing over which he could have ownership. But a person cannot be a property and so cannot be a thing which can be owned, for it is impossible to be a person and a thing, the proprietor and the property.

Id.; see also George Hegel, *Philosophy of Right* 29 § 66 (T.M. Knox trans. 1952) (arguing that alienation of personhood is "contradiction").

²⁶¹ See General Telford Taylor, *Opening Statement of the Prosecution, December 9, 1946* in *THE NAZI DOCTORS*, *supra* note 44, at 68 ("The mere punishment of the defendants ... can never redress the terrible injuries which the Nazis visited on these unfortunate peoples. For them it is far more important that these incredible events be established by clear and public proof.").

²⁶² *Id.*

²⁶³ Macklin, *supra* note 78, at 254-55.

pursuit of happiness.²⁶⁴ This third approach prohibits alienation of one's human dignity; it prohibits acts inconsistent with a respect for persons and with our ideal of human flourishing.

What do we really mean when we say our dignity is "inalienable?"²⁶⁵ Much has been written about the inalienability of certain rights, holdings, entitlements, etc.²⁶⁶ For some, problems with externalities or the costs of monitoring certain classes of transactions justify, for efficiency reasons, blocking those transactions altogether.²⁶⁷ Here, however, we are after something deeper. Our dignity is inalienable not because of the inefficiencies and costs of alienability,²⁶⁸ not as a preemptive and paternalistic blocking of classes of transactions we think people are likely to conduct rashly, but because it *is* inalienable, because that is what being a person means. As one writer put it, restrictions on alienability prevent undue "commodification" of persons.²⁶⁹ The Standard Model of informed consent, and the ethics of autonomy, dissect our persons into salable or marketable attributes, exploding the unitary vision²⁷⁰ of the person to whom dignity attaches as a person, the vision which alone gives autonomy any worth.²⁷¹

Of course, an opponent of the idea that there are limits on the ability to consent to experimentation might argue, "I have no legal moral obligations towards myself; and whatever I do to myself I do to a consenting party."²⁷² With this rationale, the

²⁶⁴ THE DECLARATION OF INDEPENDENCE para. 2 (U.S. 1776).

²⁶⁵ See Barnett, *Contract Remedies and Inalienable Rights*, 4 Soc. Phil. & Pol'y 179, 185 (1986) ("To characterize a right as inalienable is to claim that the consent of the right-holder is insufficient to extinguish the right or to transfer it to another.").

²⁶⁶ For an interesting collection of essays on problems of market justice and human dignity, see NOMOS XXXI: MARKETS AND JUSTICE (John W. Chapman & J. Roland Pennock, eds. 1989).

²⁶⁷ See, e.g., Susan Rose-Ackerman, *Inalienability and the Theory of Property Rights*, 85 COLUM. L. REV. 931, 931-32 (1985) (arguing for a broad-based approach to inalienability which allows for possible restrictions); Calabresi & Melamed, *supra* note 189, at 1093 (stating that economic efficiency is reason for allocating of entitlements).

²⁶⁸ Note that not all of these costs are economic. The costs from harm to our "moralisms" are very real and, some argue, justify inalienability rules by themselves. See Calabresi & Melamed, *supra* note 189, at 1111-12.

²⁶⁹ See Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849, 1852 (1987).

²⁷⁰ *Id.* (noting that "inalienability negates the possibility of separation" of a right from its holder).

²⁷¹ *Id.* at 1885.

²⁷² See J.M. Finnis, *Legal Enforcement of "Duties to Oneself": Kant v. Neo-*

autonomous agent who consents to a dignity-thwarting experiment affects only himself and is insulated from meddlesome external criticism. He has the capacity and right "to exercise rational autonomy in choosing and revising his ends, whatever they are."²⁷³ After all, his ends, his own ideal of human flourishing, may include living on the edge, taking risks, doing whatever it takes to acquire scientific knowledge.

Our response should be to insist that the respect due an agents' autonomy derives from our conceptually prior respect for humanity and its dignity: "[O]ne has autonomy just in so far as one does in fact make one's choices, not on the basis of one's interests, but out of respect for the demands of morality."²⁷⁴ The requirement that we respect humanity in others derives from the same universal moral law which requires that we respect humanity in ourselves.²⁷⁵ In Kantian terms, we must not make ourselves a mere means for others, but instead, always treat ourselves as ends for others.²⁷⁶ And so, when we try to dissuade, or even prevent, others from "evil forms of life," such as debasing experiments, we do so not only because they are failing in a duty to themselves—although they are—but because they are thwarting "the community's effort of reducing those evils and of maintaining forms of life more conducive to authentic human flourishing."²⁷⁷ Consequently, this argument connects nicely with the constitutional argument.²⁷⁸ "Duties to self" are really just individual and particularized instances of broader duties to protect and promote human dignity, and may be enforced by the community as part of its commitment to the good life.

Kantians, 87 COLUM. L. REV. 433 (1987). Radin notes that liberal pluralists, and advocates of the ethics of autonomy, tend to view inalienability rules as paternalistic. Radin, *supra* note 269, at 1887-88.

²⁷³ Finnis, *supra* note 272, at 439 (citing D. Richards, SEX, DRUGS, DEATH, AND THE LAW 9 (1982)).

²⁷⁴ *Id.* at 441.

²⁷⁵ *Id.* at 445.

²⁷⁶ *Id.* at 450 (citing Immanuel Kant, *The Metaphysical Elements of Justice* 236 (John Ladd trans. 1965)).

²⁷⁷ *Id.* at 456. On the importance of an ideal of human flourishing, see Radin, *supra* note 269, at 1851 (noting that "we should evaluate inalienabilities in connection with our best current understanding of the concept of human flourishing."); see also West, *supra* note 7, at 427 (arguing that we must judge our institutions by "moral value of the human personality they engender"); see generally A. MACINTYRE, AFTER VIRTUE (2d ed. 1984) (presenting and defending virtue-based notion of *eudaimonia*, or "human flourishing.").

²⁷⁸ See *supra* text accompanying notes 228-251.

Thus, the “antipaternalist’s” charge is incoherent. The prohibition of certain experiments derives not from paternalism, but from a universally applicable moral rule protecting human dignity and respect, and is therefore no more paternalistic than the prohibitions against theft and murder. When we say that humans may not be commodified, that essential attributes and features of the human person may not be alienated, that human dignity exists, and is subject to harm, above and apart from its particular manifestations in individuals, we are not exercising paternalistic judgments about the authenticity of a person’s judgment. We are simply following moral rules derived from an ideal of human flourishing. The “antipaternalist” objections to dignity-based limits on consent’s justifying power are, in the end, “the product[s] of the lonely-individual doctrine in philosophical ethics.”²⁷⁹

VI. RIGHT RELATIONSHIPS IN HUMAN EXPERIMENTATION

The history of medical research on humans is a story of triumphs and abuses.²⁸⁰ This Article has suggested that the abuses are due, in part, to our misplaced belief in and reliance on the justificatory power of consent, reflected in the Standard Model of informed consent.²⁸¹ I have suggested that although informed consent claims to respect autonomy and therefore human dignity, it fails on both counts.²⁸² The Standard Model deconstructs our choices and preferences, thereby exposing our autonomy as a plastered-over menagerie of addictions, habits, and insecurities.²⁸³ At the other end, the Standard Model rests on a shallow and unsatisfactory conception of human dignity, on an atomistic and lonely ethics of autonomy.²⁸⁴ The Standard Model is a success only in that it serves as a subterfuge, as a means of allowing us to profess a commitment to autonomy while at the same time pursuing our scientific ambitions and curiosities.²⁸⁵ But such subterfuges, while comforting and perhaps even psychologically

²⁷⁹ Thomas L. Shaffer, *The Legal Ethics of Radical Individualism*, 65 TEX. L. REV. 963, 987 (1987).

²⁸⁰ See *supra* text accompanying notes 37-52.

²⁸¹ See *supra* notes 94-95.

²⁸² See *supra* text accompanying notes 177-80.

²⁸³ See *supra* note 182 and accompanying text.

²⁸⁴ See *supra* note 180-82 and accompanying text.

²⁸⁵ See *supra* text accompanying notes 175-76.

necessary, are necessarily unstable.²⁸⁶

So why do we believe consent can justify when it is so clear that we consent to what is otherwise unjustifiable all the time? Why does consent have so much moral power; why do we often allow it to trump our other concerns?²⁸⁷ It was suggested at the beginning of this Article that our reliance on consent may reflect a weary resignation to the normlessness of modern life.²⁸⁸ In a time of so much oppression, we grab at consent as a marker of better relations; we follow it like a signpost pointing the way to our ideal of relations based on equality and respect.²⁸⁹ We are all moral relativists now; we do not know what moral laws or universal principles we could point to that would tell us which and when human experiments were unethical. But if subjects consent, we tend to believe that they are not being misused, that they have been allowed to act in an autonomous way. This is tragic, but maybe it is the best we can do. But make no mistake, the ethics of autonomy is an ethics of the second-best.

In a wonderful article on the moral force of consent, Professor Robin West describes the moral worlds of Judge Richard Posner, whom West reads as a strong proponent of consent's justificatory side,²⁹⁰ and Franz Kafka. For Posner, both autonomy and social utility are best served if we organize the world around respect for consent.²⁹¹ In Kafka's world, wretched persons in nightmarish societies consent to and get what they think they want, and are miserable.²⁹² In Professor West's view, Posner's characters use consent as a vehicle for the pursuit of economic gain and self-actualization, while Kafka's seek and crave authority and relationships of domination.²⁹³

²⁸⁶ See CALABRESI & BOBBITT, *supra* note 26, at 18-19 ("[T]he detail of the pattern of tragic choices is movement Like the arch, tragedy never rests.").

²⁸⁷ See West, *supra* note 7, at 386 ("consent is a moral trump").

²⁸⁸ See *supra* note 11 and accompanying text.

²⁸⁹ As Jay Katz puts it, we cling to informed consent as a "symbol" of respect. Katz, *Informed Consent*, *supra* note 91, at 138-39. See also Calabresi, *supra* note 27, at 403-05 (questioning whether consent is adequate indicator of decency).

²⁹⁰ "Posner's argument depends ... on an explicit assumption that the presence of consent, ... satisfies the requirements of an ideal of autonomy." West, *supra* note 7, at 385-86.

²⁹¹ *Id.* at 385 (claiming that Posner argues that moral values are furthered by wealth-maximizing market transfers where all affected parties have given consent). "Posner infers from these assumptions that the more acts of consent ... that the legal system allows ... the better off and more autonomous we will all be." *Id.* at 386.

²⁹² *Id.* at 386-87, 395-400, 406-11, 417-22.

²⁹³ *Id.* at 386-87.

We can learn from Kafka. If we use consent because we think it a marker of relations based on equality and respect for human dignity,²⁹⁴ we are mistaken. If the goal of our moral thought and lives is to attain or at least hope for such relations, consent is an insufficient vehicle. We are not simply "choosers," as the ethic of autonomy and consent posits. We are members, friends, and loved ones as well. The Standard Model ignores this fact, for it requires people who can be described without relationships.²⁹⁵ It is no wonder then that the informed consent model fails to protect our dignity. It does not understand what we are.

Perhaps we now have the beginnings of an answer. We have given consent justificatory power in human experimentation and in other contexts because, on the positive side, it is all we have and we know that consent is better than coercion. On the darker side, consent is a convenient subterfuge which allows us both to profess a commitment to dignity and autonomy and to do the research science and progress require. But what we are really after through our reliance on consent are relationships of equality and respect for human dignity. Perhaps, then, a shift in focus from the consent and state of mind of the subject and the researcher to the quality and characteristics of the relationships in which the experiment takes place will help us make better moral judgments about experimentation.²⁹⁶

Importantly, this focus on relationships neatly unifies the three perspectives, discussed above, on dignity-based limitations on consent's justifying power. A triadic, rather than dyadic, view of the experimentation transaction more accurately reflects the relationships running through and around the transaction. Our self-paternalistic, constitutional commitments are to rightly-

²⁹⁴ I owe this thought to Professor Robert Burt.

²⁹⁵ See generally THOMAS L. SHAFFER & MARY M. SHAFFER, *AMERICAN LAWYERS AND THEIR COMMUNITIES* 13-21 (1991) (stating that we must consider relationships in our dealings with others because there are things about persons that are more interesting than choices they make); Shaffer, *supra* note 279, at 965-79 (stating that organic communities of persons are prior in life and in culture to individuals); Thomas L. Shaffer & Mary M. Shaffer, *Character and Community: Rispetto as a Virtue in the Tradition of Italian-American Lawyers*, 64 NOTRE DAME L. REV. 838, 839 (1989) (arguing that human person is not simply product of his choices—"we belong" to organic communities first, and then "we choose").

²⁹⁶ See William J. Curran, Book Review, *Medical Research on Human Subjects*, 92 YALE L.J. 577, 580-81 (1983) (criticizing Levine's presentation of standard model of informed consent as insufficiently attuned to importance of relationships and context).

ordered relationships, in which equality, respect, and personal dignity are nurtured and protected. Our ideals of human flourishing which dictate that our dignity is inalienable should reflect the fact that we are beings who live in context, who live in relationships. We are not lonely automatons, but belongers; we flourish in rightly-ordered relationships.

Therefore, before deciding how much justifying force to give consent, we ought to assess the quality of the relationship which emerges or results from the proposed transaction.²⁹⁷ When we experiment on prisoners, persons dying of AIDS, or children, what kinds of relationships are we creating and exploiting?²⁹⁸ In these relationships, in which we observers are also invisible participants, are all parties seen and regarded as equals? Are all respected as human persons? The desperate person dying from AIDS who is willing to undergo any experiment for the slightest chance of survival may well be able to consent intelligently and autonomously, and our refusal to participate may well block the exercise of his autonomy, but it may also reflect our commitment to certain kinds of relationships and to a morality whose essential experience is not the act of consent. When we tell Doe that we will not perform psychosurgery on him, we should do so not because he cannot consent, but because the relation between state and prisoner has already strained our commitment to equality and human dignity. We do not care if Doe consents because our concern is that his consent would produce a relation even further from our ideal.²⁹⁹

²⁹⁷ See West, *supra* note 7, at 423-24 ("An assessment of the moral value of that to which we ... consent must include an assessment of the relationship flowing from the transaction [C]onsent ... may have good or evil consequences, depending upon the ... moral quality of the relationship ... that our consent nurtures."); Radin, *supra* note 269, at 1904 (arguing for an ideal of human flourishing based on "contextuality" and noting that "[i]n order to be autonomous individuals, we must at least be able to act for ourselves through free will in relation to the environment of things and other people.").

²⁹⁸ See Burt, *supra* note 47, at 34 (insisting that we should not allow psychosurgery in prison "until everyone could see that the operation would not increase the distance, the gulf, the differences, between the prison population and the rest of us").

²⁹⁹ See Burt, *supra* note 10, at 15 (discussing tension between criminal law and commitment to equal respect among persons, and noting in particular that death penalty is "flamboyantly visible proclamation that all social relations between victim and oppressor ... have been irreversibly severed"); see also West, *supra* note 7, at 395, 409 (noting that community's failure to respond to consent-driven human degradation is "moral failure" by that community, and "breakdown of community and

Ms. Eva Mozes-Kor, a survivor of Mengele's experiments on twins, wrote:

[I]f a human being is ever used in the experiments, the scientists must make a moral commitment never to violate a person's human rights and human dignity ... The scientists of the world must remember that the research is being done for the sake of mankind and not for the sake of science; scientists must never detach themselves from the humans they serve.³⁰⁰

This is the correct approach. We must be committed to relations of nondetachment—precisely the opposite of the relations produced by a mistaken fidelity to consent's justificatory side, to the atomistic, separated, lonely ethics of autonomy.³⁰¹ A hollow and specious commitment to autonomy which looks only for consent and then robs consent of its moral force when the results of autonomy are for any reason unacceptable does not honor the lessons of Nuremberg and of the ongoing history of human experimentation. In the context of human experimentation at least, we must place objective limits on what we permit ourselves to do to each other, limits that remind us to look at the relationships we create in our political and social lives.³⁰²

EPILOGUE: FAITH AND HOPE

This Article has made several references to religious sources and authorities, which I think were both appropriate and helpful supports for the discussion. But these references suggest some-

brotherhood").

³⁰⁰ Eva Mozes-Kor, *The Mengele Twins and Human Experimentation: A Personal Account*, in *THE NAZI DOCTORS*, *supra* note 44, at 53, 58. See also *CATECHISM*, *supra* note 255, at § 2293 ("Science and technology are ordered to man, from whom they take their origin and development; hence they find in the person and in his moral values both evidence of their purpose and awareness of their limits.").

³⁰¹ See Ann Althouse, *Standing*, in *Fluffy Slippers*, 77 U. VA. L. REV. 1177 (1991) (discussing how Court mistakenly viewed Gary Gilmore, from Norman Mailer's *The Executioner's Song*, in isolation, apart from complex social relationships his execution affected); *SHAFFER & SHAFFER*, *supra* note 295, at 880 ("An anthropology of rights ... seems always to depend on the premise that the human person is fundamentally alone.").

³⁰² See Richard John Neuhaus, *The Way They Were, The Way We Are: Bioethics and the Holocaust*, *FIRST THINGS*, March, 1990, at 36.

A rabbinical dictum has it that we should 'place fences around the law.' The idea is that restraints and prohibitions should be in place to prevent us from reaching, or at least impede our progress toward, the point of absolute and damning transgression. There should at least be safety rails around the abyss.

Id.

thing else as well. For persons living in a community of faith, the normlessness of radical individualism may weigh less heavily, because there is an alternative.³⁰³ Not only may faith help provide content to the ideals of human dignity and flourishing, it may help implement this ideal in practice.

If the ideal of our moral life is a world of relations which respect and promote human dignity, where justice is not only transactional but consists, as Plato saw, of rightly-ordered relationships, then faith permits us to hope that our God will participate in our relations with each other, and that God also desires and respects the dignity of persons. Our faith may also teach us that our failure to protect and promote others' dignity, and our excusing of our complicity in inhumanity through reliance on consent, is not merely bad policy but a sin.³⁰⁴ In the end, we just do not know how to best promote and value human dignity. Perhaps, this side of Heaven, we can only aim at our ideal.

³⁰³ In other contexts, Professor Thomas Shaffer has written a great deal about the competing claims of radical individualism and faith communities. See Shaffer, *supra* note 279, at 986-91; SHAFFER & SHAFFER, *AMERICAN LAWYERS AND THEIR COMMUNITIES*, *supra* note 295, at 196-217; THOMAS L. SHAFFER, *FAITH AND THE PROFESSIONS* (1987).

³⁰⁴ See West, *supra* note 7, at 411 ("Excusing one's own inhumanity by protecting the freedom of the loser to suffer is ... a type of sin.").